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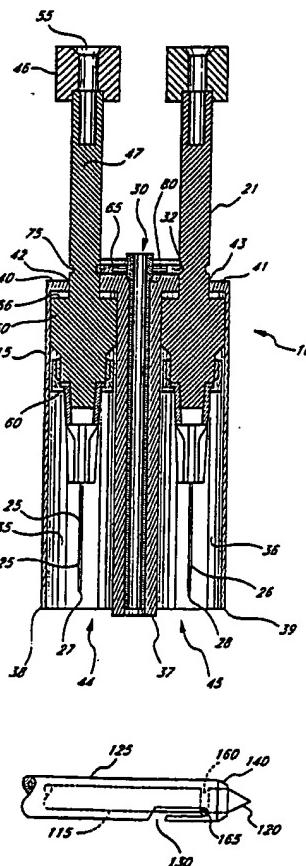
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :  A61B 17/16, 17/04		A2	(11) International Publication Number: WO 93/10715  (43) International Publication Date: 10 June 1993 (10.06.93)
(21) International Application Number: PCT/US92/10451 (22) International Filing Date: 3 December 1992 (03.12.92)			(74) Agents: ALTMAN, Daniel, E. et al.; Knobbe, Martens, Olson & Bear, 620 Newport Center Drive, Suite 1600, Newport Beach, CA 92660 (US).
(30) Priority data: 801,747 3 December 1991 (03.12.91) US			(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published <i>Without international search report and to be republished upon receipt of that report.</i>
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(54) Title: SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE

(57) Abstract

The surgical treatment of stress urinary incontinence can be improved by modifications that increase safety, efficacy and reproducibility. Thirty women with stress urinary incontinence underwent consecutive endoscopic bladder neck suspension with modifications designed to achieve those goals. Those modifications included: 1) a technique of probe passage to avoid injuring the bladder and to provide a more accurate and reproducible capture of the pubocervical fascia lateral to the bladder neck and urethra, 2) anchor fixation of the suspending sutures to the pubic bone to decrease the risk of suture pull through from above and to decrease post-operative pain and 3) a simple and reproducible technique to set a limited tension of the suspending sutures. procedures were outpatient or with one day of hospitalization beyond the day that their catheter was removed. The immediate post-operative success rate was 100 %. There was one failure in a follow-up to 8 months. Urinary urgency dropped from 63 % pre-operatively to 17 % post-operatively. The patients' satisfaction with the procedure was high. A description of these modifications and results of procedures with these modifications are disclosed. Novel drill guides suture passers and suture tensioners for use in the surgical method are also disclosed.



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### SURGICAL TREATMENT OF STRESS

#### URINARY INCONTINENCE

##### Background of the Invention

The present invention relates to the treatment of stress urinary incontinence "SUI," and, in particular, to improved methods and surgical devices for the surgical treatment of SUI in females. The devices disclosed herein are additionally useful in a wide variety of other surgical procedures.

Genuine stress incontinence is the involuntary loss of urine due to a sudden rise in intra-abdominal pressure. It has been estimated that between 40% and 50% of young, healthy nulliparous women admit to occasional mild stress incontinence; however, at least 80% of stress incontinence patients are in the perimenopausal age group and are multiparous. Raz<sup>3</sup> has suggested that the female urethral continence mechanism is dependent on the interaction of four urethral factor: urethral closing pressure, urethral length, urethrotrigonal anatomy, and urethral reception of intra-abdominal pressure.

The urethral closing pressure is predominantly a result of the interaction of smooth and striated muscle sphincter activity, but there is also some contribution by nonmuscular urethral factors such as the submucosal vascular plexus, the elastin and collagen content of the urethral tissues, and a sphincter like effect of the mucosa. There has been considerable diversity of opinion regarding the anatomic structure and the innervation of the urethral sphincters, and a variety of views have been expressed in the literature.

Lapides and associates have stressed the importance of urethral length in the maintenance of continence in the female. However, although it certainly interacts with other factors to contribute to continence, a short urethra alone will not produce incontinence. Urethral length varies considerably in normal women, and women with proven genuine stress urinary incontinence do not invariably have urethral shortening.

Urethrotrigonal anatomy, which can be demonstrated by

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lateral cystourethrography, should fulfill certain criteria. The bladder base should lie above the level of the inferior ramus of the symphysis, and with straining should not descend more than 1.5 cm. There should be a normal urethrotrigonal alignment with an angle normally less than 100 degrees, and the urethral axis should be approximately 35 degrees from the vertical. In the hypermobile situation loss of all of the normal anatomic features may occur, a radiologic finding that correlates with the clinical finding of cystourethrocele. However, clinical experience has shown that the coexistence of cystourethrocele and incontinence does not predict that the incontinence is of a genuine stress variety.

The transmission of intra-abdominal pressure to the intra-abdominal portion of the proximal urethra is also reported to be important in the maintenance of continence. This is a passive phenomenon, and is the result of the normal anatomic configuration just described. Whenever there is a rise in intra-abdominal pressure during such stresses as coughing or straining, the pressure is transmitted not only to the bladder but also to the proximal urethra, with resultant increase in the closing pressure, and prevention of leakage. If the urethral axis is altered, rotational descent will drop the proximal urethra and bladder base from its intra-abdominal location, and will obviously impair such pressure transmission.

A wide variety of operations have been used to correct this condition, generally involving the principles of elevating the bladder neck anteriorly and/or elongating and narrowing the proximal urethra. One of the most popular operations today for female stress incontinence is the Marshall-Marchetti-Krantz vesicourethropexy. It has at least an eighty-five percent success rate, against which other operative success rates must be measured. Recently, the Pereyra operation and its modifications have enjoyed some popularity.

Notwithstanding the foregoing, however, there remains a need for an improved treatment for SUI. Preferably, the

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treatment is as noninvasive as possible under the circumstances, and will eliminate or minimize hospitalization and the use of general anesthetics. In addition, there remains a need for improved medical instrumentation such as  
5 drill guides and suture passers for use in connection with SUI treatment and other medical procedures.

Summary of the Invention

There is provided in accordance with one aspect of the present invention a drill guide for directing a drill bit at a selected site on a bone. The drill guide comprises a housing, and at least two chambers extending axially within the housing. Each of the chambers has an opening at the distal end. A plunger is provided in each of the chambers, each plunger axially movable from a first retracted position to a second extended position. A probe is mounted on the distal end of each of the plungers, and adapted for retraction within the open end of the chamber and extension outside of the open end of the chamber. In a simplified embodiment, each of two or more probes is axially movably disposed within the housing, without the use of a distinct plunger. A drill guide channel extends axially through the housing, within a plane parallel to the plane joining the axes of the first and second chambers, and in between the axes of the first and second chambers.  
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Preferably, one or both of the plungers is provided with a releasable lock for releasably retaining the plunger in the retracted position, thereby minimizing the likelihood of accidental needle sticks. The preferred probe comprises a hypodermic needle or a sharpened solid wire. In a two probe embodiment, the axes of the first and second probes are separated by a distance within the range from about .5 to about 1.5 cm. Preferably, the axis of the drill guide channel is approximately equidistant from the axes of each of the probes.  
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In accordance with the further aspect of the present invention, there is provided a method of positioning a drill guide over a drilling site on bone, comprising the steps of

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providing a drill guide of the type having a housing, at least two axially extendable probes within the housing, and a drill guide extending through the housing. A first probe is extended from the retracted position to the extended position, 5 and advanced through the tissue until it contacts a bone. The second probe is thereafter extended from the retracted position to the extended position, until the second probe contacts the bone. If the first extension of the second probe does not result in a contact, both probes are retracted within 10 the housing, and the drill guide is translated along the sagittal axis. The first probe is thereafter reextended and the foregoing steps are repeated until both the first and second probes contact the bone.

In accordance with another aspect of the present invention, there is provide a method of installing a bone anchor in a bone, utilizing the drill guide defined above. In 15 accordance with the installation method, each of the probes is sequentially extended and advanced through tissue as described until each of said probes is in contact with the bone. A drill bit is thereafter advanced through the drill guide channel and a hole is drilled in the bone. The drill bit is thereafter withdrawn from the drill guide channel, and a suture anchor is advanced through the drill guide shaft and 20 into the bone.

In accordance with another aspect of the present invention, there is provided a suture passer of the type adapted for releasably retaining a suture. The suture passer comprises a handle, and an elongate tubular probe guide 25 extending in a distal direction straight or curved from the handle. An elongate probe is axially movably disposed within the tubular probe guide, for motion between a first retracted position and a second extended position in which the sharpened distal tip of the probe is exposed. An annular recess is provided on the probe, to cooperate with an opening on the tubular guide for receiving a suture. The probe is axially 30 movable with respect to the probe guide between a first position in which the annular recess is aligned with the

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opening for receiving a suture therein, a second position wherein the annular recess is out of alignment with the opening, to trap or retain a suture therein and a third position in which the distal probe tip is exposed.

5 In accordance with a further aspect of the present invention, there is provided a surgical bladder neck suspension procedure, for the treatment of stress urinary incontinence. In accordance with the method, a technique of creating a suspension web comprising a plurality of lengths of  
10 suture is constructed extending between the pubocervical fascia and the pubic bone, on each of the right and left sides of the midline. Sutures are carried through tissue utilizing the suture passer disclosed herein, and sutures are tied down to the pubic bone utilizing a bone anchor positioned on each  
15 of the right and left sides of the midline by a drill guide as disclosed herein. Prior to tying, sutures are appropriately tensioned by advancing the suture around the suture tensioner disclosed herein and tying in a conventional manner. Thereafter, the suture tensioner is removed and the surgical  
20 site prepared and closed in a conventional manner.

These and additional features and advantages of the present invention will become apparent from the detailed description of preferred embodiments which follows, when taken together with the attached drawings and claims.

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Brief Description of the Drawings

Figure 1 is an elevational partial cross sectional schematic view of a drill guide in accordance with the present invention.

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Figure 2 is a cross sectional view along the lines 22 in Figure 1, showing the actual orientation of the drill guide channel with respect to the probes.

Figure 3 is a side elevational schematic view of the drill guide of Figure 1.

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Figure 4 is a front elevational view of the drill guide shown in Figure 3.

Figure 5 is a cross sectional view of a suture passer in accordance with the present invention.

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Figure 6 is an enlargement of the distal tip of the suture passer illustrated in Figure 5.

Figure 7 is a perspective and detailed view of the suture tensioner in accordance with the present invention.

5 Figure 8 illustrates the location of incision sites for the method of the present invention.

Figure 9a represents the positioning of the vertical passage of a Stamey needle to just below the rectus fascia.

10 Figure 9b illustrates the placement of a needle point on the underside of the pubic bone.

Figure 9c represents the distal passage of the needle to the level of the introitus.

15 Figure 9d represents the withdrawal of the needle from the pubourethral ligament and the path of the sweep back along the pubocervical fascia to the area of the bladder neck and first entry site.

Figure 10a illustrates the initial passage of the needle through the pubocervical fascia at point 1 (proximal and medial).

20 Figure 10b represents the withdrawal of the suture through the pubic wound.

Figure 10c illustrates the passage of the needle through the lateral aspect of the pubic wound and through the pubocervical fascia at point 2 (proximal and lateral).

25 Figure 10d illustrates the withdrawal of the suture into the retropubic space.

Figure 10e illustrates the passage of the needle and suture through point 3 (distal and medial).

30 Figure 10f illustrates withdrawal of the needle into the retropubic space.

Figure 10g illustrates the passage of the needle through point 4 (distal and lateral).

Figure 10h illustrates the withdrawal of the suture through the pubic wound.

35 Figure 11a illustrates an early generation Mitek G1 anchor.

Figure 11b illustrates a Mitek G2 anchor.

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Figure 12a illustrates drilling a hole in the pubic bone for placement of an anchor.

Figure 12b illustrates placement of an anchor with a suture into the pubic bone using an anchor inserter.

5 Figure 12c illustrates extraction of the inserter leaving an anchor and suture in place.

Figure 13a is an end-on view of the urethra emphasizing volume of pubocervical fascia captured and showing relative locations of suture entry points.

10 Figure 13b is a lateral view emphasizing the length of pubocervical fascia captured from the bladder neck to the pubourethral ligament.

15 Figure 14 illustrates the tying of the suspension suture on pulp of finger leaving a small amount of suture slack when finger is removed.

Figure 15 illustrates the duration of hospitalization following surgery of the patients discussed in Example 1.

20 Figure 16 illustrates the period of intermittent catheterization following removal of in-dwelling catheter for the patients discussed in Example 1.

Figure 17 illustrates urinary urgency before and after surgery for the patients discussed in Example 1.

25 Figure 18 illustrates patient subjective satisfaction with results of the procedure conducted in accordance with the present invention, for patients discussed in Example 1.

#### Detailed Description of Preferred Embodiments

SUI is generally curable with any of a variety of surgical procedures that properly suspends the bladder neck. However, limitations of known procedures include 1) the extent of surgical morbidity 2) the ever present threat of long term failures and 3) the reproducibility between different surgeons.

30 Pereyra<sup>1</sup> introduced the transvaginal bladder neck suspension as a less invasive alternative to open retropubic procedures. Stamey<sup>2</sup> limited morbidity and improved the reproducibility of the transvaginal bladder neck suspension by introducing endoscopic control and confirmation of suture

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placement. Raz<sup>3</sup> has improved reproducibility by introducing full palpitory control of needle passage through the retropubic space, thereby limiting disability through injury to the bladder or other retropubic structures.

5       The distal passage of the suture passer disclosed herein or other needle followed by a sweep back to the bladder neck area described herein accomplishes a similar goal but without the necessity of entering the retropubic space. Passage of the needle point to the level of the introitus along the underside of the pubic bone obviates the need to turn the needle down toward a bladder neck that has been digitally elevated, thereby reducing the risk of bladder injury. Extraction of the needle from the pubourethral ligament is necessary to allow a "capture" of the more pliable pubocervical fascia alongside the urethra. The subsequent, 10      gentle sweep back of the needle along the surface of the pubocervical fascia provides an easy and safe means of introducing the needle to the bladder neck area under the vaginal digital guidance.

15      Gittes and Loughlin<sup>5</sup> have further popularized the technique of Pereyra and demonstrated an advantage of increased long-term efficacy by creating an autologous bolster with the transvaginal passage of a curved needle. As an alternative manner of creating an autologous bolster, the proposed modification described herein uses the suture passer disclosed herein, or a Stamey needle through a suprapubic approach to carry the suture through all of its vaginal passes. The full carriage of the suture by the suture passer needle offers the benefits of 1) improving accuracy and 20      reproducibility by allowing palpation of the needle at each vaginal entry point in reference to the bladder neck and catheter, 2) potentially decreasing morbidity by reducing the risk of injury and/or irritation through inadvertent entry into any part of the urethra or bladder and 3) possibly contributing to long term efficacy by assuring that a full thickness layer of pubocervical fascia is captured. This 25      technique permits the capture of a large lateral volume of 30      35

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pubocervical fascia similar in an area to that available for suturing in an open retropubic urethropexy.

Leach<sup>4</sup> has limited morbidity by decreasing post-operative pain and has potentially improved long-term efficacy with pubic fixation of the suspending sutures. However, the trochar needle passage through the pubic bone as described by Leach can be difficult through the limited exposure that is used with some forms of endoscopic bladder neck suspension. Other various forms of pubic bone fixation have also been described with transvaginal and open bladder neck suspension surgery<sup>6,7,8</sup>. To facilitate the anchoring of the suspensory suture to the pubic bone with minimal soft tissue dissection, the present inventor has used a new set of devices called the Mitek Anchor System. The latest generation of Mitek anchor, the G2, consists of a titanium body coupled to nickel-titanium arcs. These anchors have recently been used most commonly for tenodesis and ligamentous reconstruction of the shoulder and foot<sup>9,10</sup>.

In the present setting of bladder neck suspensions, the Mitek anchor with attached suture is passed into a hole drilled in the pubic bone. Care must be taken to assure that the hole has been drilled into the pubic bone and not inferiorly through the tendon of the adductor longus or superiorly through the rectus fascia over the surface of the pubis. Proper location of the drill and placement of the bone anchor in the bone is facilitated by the drill guide illustrated in Figures 1-4 and discussed infra.

Once the anchor is passed into the bone, the anchor's unique memory forces the arcs to spring open to their original shape and to engage in the cancellous portion of the pubic bone. The complication of infection with use of the anchor has not been noted, which may, in part, be due to the emphasis on broad spectrum antibiotics and sterile technique with use of video endoscopy, when possible.

Anchor pubic bone fixation in one study by the inventor herein was associated with a limitation of post-operative pain allowing the procedure to be performed on an outpatient basis

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in many of the patients. Pubic anchor fixation may limit suspending suture pull through at the level of the rectus fascia. Any assessment of resultant improvement of long term efficacy will require longer follow-up.

5        Certain specific embodiments of the methods and devices of the present invention will follow, together with an example of the inventive bladder neck suspension procedure.

#### I. DRILL GUIDE

10      In accordance with one aspect of the present invention, there is provided a drill guide for locating drill sites inside a patient's body. More specifically, the invention relates to a multi-probe bone locator and drill guide centering device for locating a desired site on a bone, guiding a drill bit to the located site, retaining access to the site following drilling, and installation of a bone anchor for anchoring sutures.

15      Referring to Figure 1, there is shown a surgical drill guide 10 in accordance with one aspect of the invention. Generally, drill guide 10 comprises a body 15 carrying two or more plungers 20, 21, each having a bone probe 25, 26 at its end. A guide shaft 30 is located between two adjacent bone probes 25, 26. Alternatively, one or more of the plungers 20, 21 can be eliminated, so that one or more probes 25, 26 is directly mounted within or to body 15. Thus, in a simplified design, a drill guide channel is held in proximity to two or more elongate probes such as hypodermic needles which are preferably axially movable.

20      Body 15 is the support structure for the drill guide 10. The body 15 may have any of a variety of exterior configurations; however, it is preferred that the body be sufficiently axially elongate to facilitate withdrawal of the sharpened distal tips 27, 28 of the probes 25, 26 therein to minimize accidental needle sticks, and generally oval or rectangular in cross section. See, e.g., Figure 2. The 25      inside of the body 15 has two or more identical chambers 35, 36 spaced apart from each other to accommodate a drill guide shaft 30, as will be discussed. Preferably, an annular tissue

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compression portion 37 of body 15 adjacent the guide shaft 30 extends slightly farther in the distal direction than the lateral sidewalls 38, 39 of the body 15. Tissue compression portion 37 is optimally provided with a rough or serrated edge surface for contacting the tissue surrounding the drill site as will be discussed.

Each chamber 35, 36 extends from the distal end of the body 15 to a point near the proximal end of the body 15. In this manner, chambers 35, 36 are provided with open distal ends to permit reciprocal axial motion of the bone probes 25, 26 therethrough. Proximal ends of chambers 35, 36 are provided with a stop such as end walls 40, 41 having central passageways 42, 43 therethrough for movably accepting the plungers 20, 21. Similarly, distal ends 44, 45 of chambers 35, 36 can be provided with an end wall (not illustrated) having a probe opening therein, or a pierceable septum for permitting passage of probes 25, 26 therethrough.

The exact distance between the axes of adjacent chambers 35, 36 depends on the procedure for which the device is to be used. For example, in a bladder neck suspension procedure, the axes of chambers 35 should be separated by a distance of no more than about 10 mm from their centerlines, in an embodiment having coaxial probes and plungers, so that the corresponding probe separation is also no more than about 10 mm. Preferably, the separation between adjacent probes is within the range of from about 5 mm to about 15 mm.

Due to the bilateral symmetry of the illustrated embodiment, only one side will be particularly described below. The plunger 20 preferably comprises three main portions: an engaging knob 46, a main shaft 47 and a stop 50. The knob 46 is generally a cylindrical body attached to the top of the shaft 47 and shaped for easy engagement with a thumb or hand. This knob 46 may be attached to shaft 47 in a variety of manners. For example, knob 46 is illustrated as having a recessed portion on its distal surface for accepting the proximal end of shaft 47. A screw 55, preferably flat headed, is then passed through the top of the knob into the

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top of the shaft 47 to securely lock them together. Alternatively, the shaft 47, knob 46 and stop 50 can be integrally molded from any of a variety of thermoplastic materials well known in the art of surgical instrument manufacturing.

The plunger shaft 47 extends from the knob 46 through the opening 42 in the proximal end wall 40 of the body 15 and into chamber 35. Shaft 47 preferably is at least about 25 mm long from the distal surface of the knob 46 to the proximal surface of end wall 40 on body 15. In this manner, the plungers 20, 21 have a sufficient range of axial travel between a first, retracted position in which the distal tips 27, 28 of probes 25, 26 are shielded, and a second, extended position in which the distal tips 27, 28 of probes 25, 26 are exposed. It is contemplated, however, that the length of the shaft 47, probe 25 and axial travel may vary depending on the intended procedure.

A stop 50 is positioned on the distal end of the shaft 47. The stop 50 and shaft 47 may either be separately fabricated or may be fashioned from one piece of material such as by known molding or lathing techniques. The illustrated stop 50 comprises a radially outwardly extending portion of the plunger 20 which travels within the chamber 35 to produce a transverse abutment surface 56. The stop 50 thus limits the proximal range of travel of the plunger 20 by engagement of the abutment surface 56 with the distal surface of end wall 40 of the body 15. The stop 50 is preferably provided at its distal end with a connector such as a standard luer for attachment of a probe 25. As will be appreciated by one of skill in the art, any of a wide variety of interlocking or complementary surface structures can be devised to accomplish the function of stop 50.

In the illustrated embodiment, the probe 25 is inserted into a threaded cap 60. This cap 60 is preferably threaded on its interior surface so that it may be attached to the correspondingly threaded distal end of stop 50. Alternatively, the probe 25 can be connected to the stop 50 or

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shaft 47 such as by molding the proximal end of the probe 25 therein.

Each probe 25, 26 extends from the corresponding shaft 47 towards the distal end of the chamber 35. Probe 25 may 5 comprise standard hypodermic tubing such as a standard needle, or a solid wire probe preferably having a sharpened distal end.

The length of the probe 25 is preferably such that when 10 the plunger 20 is in a fully retracted state, the distal end of the probe 25 is spaced by at least about 4 mm from the open distal end of the chamber 35. In this manner, the probe end is protected against contamination and the user of the drill guide 10 is protected against accidental probe sticks. Alternatively, the probes 25, 26 can be rigidly secured to the 15 body 15 or directly to a tubular drill guide shaft 30 as will be apparent to one of skill in the art.

In an embodiment having axially movable plungers, the 20 plunger 20 is normally retracted proximally such that the distal tip 27 of probe 25 connected thereto is recessed from the distal end 44 of the chamber 35. This position is preferably releasably maintained by engaging rods 65 which are biased in the direction of annular recess 75 in the shaft 47 of the plunger 20.

In the illustrated embodiment, annular recess 75 is 25 provided in the plunger shaft 47 at a point adjacent the proximal end of the body 15. When the plunger 20 is retracted, recess 75 releasably receives rod 65. This rod 65 is biased such as by a spring so that it provides an interference fit within recess 75 and holds the plungers 20 in their retracted position. The rods 65 and springs are 30 preferably mounted within a housing adjacent the proximal end of the body 15.

A drill guide shaft 30 extends axially in between the two 35 chambers 35, 36 containing the plungers 20, 21. Preferably, drill guide shaft 30 is disposed approximately equidistant from the longitudinal axis of each of chambers 35, 36 so that when each of the probes 25, 26 is in contact with a bone, the

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axis of drill guide shaft 30 will be spaced well away from the edge of the bone. In addition, in the illustrated embodiment, the axis of shaft 30 is offset laterally from the plane connecting the axes of chambers 35 so that the axes of the two probes and the drill guide shaft 30 are disposed on vertices of a triangle. See Figure 2. This configuration facilitates the use of a slot 31 extending the length of guide shaft 30 for receiving a suture during the installation of the suture anchor.

Drill guide shaft 30 is optionally surrounded by an elongate tubular bushing 80 extending throughout at least a portion of the body 15, and preferably positioned so that the distal end of the bushing 80 is slightly recessed from the distal portion 37 of body 15. This bushing 80 aids in properly centering a later installed drill bit and acts as a channel through which a suture anchor is introduced into the hole after drilling.

Referring to Figure 3, there is disclosed a handle 90 connected to the outside of the body 15 for maneuvering the drill guide 10. This handle 90 is preferably generally tubular in shape, and approximately 10 mm in diameter for easy gripping by the user. The handle 90 as illustrated extends from its connection with the body 15 laterally away from said body, then upward and outward at an angle, and finally ends in a gripping section 91 which extends generally along a perpendicular to the axis of the body 15. This handle design permits the user to forcefully press the drill guide 10 against the body, as well as to facilitate controlled translation of the drill guide along a sagittal axis.

The handle 90 may be connected to the body 15 in any of a variety of conventional manners. In the illustrated embodiment, the handle extends into a small recess in the body 15 and then is locked in place such as with a nut 85. The nut 85 as illustrated has a threaded portion for engaging the body, and a locking portion for pushing the handle 90 into the body 15. Alternatively, the handle 90 can conveniently be integrally molded with body 15, or secured thereto such as by

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thermal or solvent bonding techniques or by adhesives well known in the art.

It is preferred that the components of the drill guide 10 be made of a material which is sterilizable, relatively rigid 5 and biocompatible, such as stainless steel or any of a variety of polymers conventionally used for medical instruments of the type designed to enter the sterile field.

The operation of the surgical drill guide 10 will now be described. When it is desired to locate a bone for attachment 10 of a suture anchor therein, the drill guide is placed on the body over the area of the bone. The drill guide 10 is centered after visualization or digital palpation over the bone.

The user pushes one or both of the knobs 46 to distally 15 extend at least a first probe 25. The probe 25 is extended into the body by pushing the plunger 20 down, until either the plunger has been fully extended or the bone is contacted.

If the plunger extends fully without the probe contacting the bone, the probe is retracted and drill guide 10 is then 20 repositioned for another attempt at locating the bone.

When the first probe 25 does engage the bone, pressure is released from the knob 46. The user then extends the second probe 26 by pushing on the corresponding knob of the second plunger 20. Once again, the second probe 26 will either 25 engage the bone or the plunger 20 will fully extend without contact. If no contact is made by the second probe 26, it is retracted again by pulling upward on the appropriate knob. The drill guide 10 may then be translated along the sagittal axis and one or both probes reextended.

This process is continued until both probes 25, 26 30 contact the bone. At this time, the user will be assured that the bone has been located and that the guide shaft 30 is properly centered over the bone.

A drill bit is then extended through the drill bushing 80 35 and into the patient. The drill bit is used to drill through adjacent tissue and produce a small hole in the bone. Preferably, a step drill or other limiting structure is

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utilized for producing a hole having a predetermined and reproducible depth into the bone. For installation of the preferred Mitek G2 anchors disclosed herein, a 2.5 mm diameter drill bit is used to produce a hole of 15 mm depth into the bone.

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The desirability of having a tissue compression portion 37 which extends distally slightly beyond the distal end of the adjacent body is now apparent. At the time the drill bit is retracted, the hole drilled would normally close upon itself because of the resiliency of the surrounding tissue. However, by maintaining pressure on the body 15 in the direction of the bone, the tissue compression portion 37 tends to compress the adjacent tissue thereby minimizing migration and maintaining the hole open.

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In this manner, the tissue located directly under the guide shaft is prevented from closing, and the anchor can be readily advanced through guide shaft 30 and into the bone. Even without distally extending tissue compression portion 37, installation of the anchor is greatly simplified using the drill guide of the present invention because the axis of drill guide shaft 30 remains directed at the drill hole.

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Following retraction of the drill bit, a suture anchor is advanced into the body through the drill bushing 80 and then connected within the hole in the bone. An installation tool which facilitates holding the anchor body by means of an interference fit at the gripping point and guiding said anchor through the guide hole and compressed tissue into the bone hole is preferably utilized. The suture, typically previously connected to the anchor, is permitted to trail out through the slot 31 provided for that purpose.

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II. SUTURE PASSER

In accordance with another aspect of the present invention, there is provided a suture passer adapted for grasping and passing internal sutures, such as to construct the sling disclosed herein. The suture passer of the present invention is particularly suited for use in connection with such surgery as the bladder suspension procedure disclosed

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herein, where sutures are required to be advanced and withdrawn without direct visualization and through relatively long distances. Alternatively, the suture passer may be used with other techniques such as Pereyra, Stamey and Gittes methods.

The suture passer of the present invention enables the clinician to avoid accidental damage to the patient's internal structures and accidental needle sticks to himself and operating room personnel. The passive retraction of the 10 needle point within the cannula, which will be discussed, facilitates the foregoing safety features, and secure capture of the suture material. The ability to advance the cannula with a blunt (retracted needle tip) end also facilitates internal suturing without direct visualization. Safe direct 15 tactile feedback is provided along organ surfaces to localize placement of the suture. These and other features and advantages of the suture passer of the present invention will be discussed below.

Referring to Figure 5, there is disclosed a suture passer 20 105 in accordance with one aspect of the present invention. In general, suture passer 105 comprises a handle 110, an axially movable probe 115, and a probe guide 125 having a suture channel 130. Details of suture channel 130 and related structures can be seen in the enlarged view in Figure 6.

Handle 110 serves both as a gripping area for the user 25 and as a support structure for the suture passer 105. Handle 110 preferably comprises a hollow tubular body having proximal end wall 111 and distal end wall 112. Handle 110 is preferably of such a size to be easily gripped by a user. A handle 110 being at least approximately .75 inches (20 mm) in 30 diameter and 4 inches (110 mm) in length has been found to work well. Preferably, handle 110 is provided with knurling or other surface texturing to produce a high friction gripping surface.

A support 135 is preferably mounted such that it extends 35 from the distal end of the handle 110 to provide a mounting support for probe guide 125. The support 135 as illustrated

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is provided with a generally cylindrical proximal section 137 for engagement within the distal end of the handle 110 and a tapered distal section 139 for securing probe guide 125. The support 135 acts as a transition member from the handle 110 to support the probe guide 125.

The probe guide 125 comprises an elongated tubular member which is at its proximal end inserted within or secured to the support 135. The probe guide 125 may be fixed to the support 135 in any variety of manners, including brazing, threading or others known in the art.

The probe guide 125 extends distally therefrom and is preferably within the range of from about 6 inches to about 8 inches in length and may be straight or curved. The length of probe guide 125 may vary, of course, depending on the exact intended procedure.

At its distal end, the probe guide 125 is provided with a smooth tapered engaging face 140. The distal extreme of tapered face 140 is slightly rounded or polished so that it can be pressed lightly against and swept along the surface of tissue such as the pubocervical fascia without cutting or traumatizing the tissue.

The probe guide 125 is preferably no more than about .1 inches (2.5 mm) in diameter and is provided with at least one central lumen for acceptance of an axially movable probe 115. An elongate probe 115 is mounted within the handle 110 and extends through the support 135 and the probe guide 125. Probe 115 is preferably provided at its proximal end with a relatively large diameter body portion 116 adapted for reciprocal motion within tubular handle 110. Body portion 116 is preferably provided with a slightly smaller diameter recessed portion 117 for receiving a return spring 142 which biases the probe in the proximal direction. Alternatively, any of a variety of means can be utilized to provide a proximal bias on probe 115.

The length of body portion 116 is less than the axial length of the cavity within handle portion 110 so that the body portion 116 has an axial range of motion within the range

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of from about 2 mm to about 10 mm, and preferably about .12 inch (3 mm). The proximal end wall 136 of support 135 which extends into the handle 110 acts as one limiting stop for distal travel of body 116. The distal surface of end wall 111 limits proximal travel of body 116. Spring 140 pushes against an annular shoulder 118 on body portion 116, biasing the probe 115 proximally.

The distal end of probe 115 is provided with a sharpened tip 120. Spring 142 normally biases tip 120 towards a first retracted position within the distal end of probe guide 125. Axial distal force on body portion 116 extends tip 120 into a second exposed position as illustrated in Figures 5 and 6. Although the probe 115 may be actuated in any number of ways, such as by use of a knob or button, it is presently preferred that a rotatable cam 122 be used.

The cam 122 is attached to a post 150 which extends proximally from the handle 110. The cam 120 is rotatably mounted about a pin 155 which extends in an axis perpendicular to the longitudinal axis of the probe 115. The proximal end of the body portion 116 has a rod 145 which extends proximally through an opening 147 in the proximal end wall 111 of the handle 110.

The cam 122 has at least a two position engaging surface which, when rotated into position, engages the rod 145 of the body 116. In a first position, the bias imposed by return spring 142 is overcome and the sharpened distal end 120 of probe 115 is extended outwardly from the probe guide 125. In a second engaged position, the distal end 120 remains within probe guide 125, but the suture lock is actuated as will be discussed. In a third position, the distal tip 125 is passively fully retracted within guide 125, and the suture lock is open such as for receiving or releasing a suture.

The cam 120 is preferably provided with an actuator portion 156 which extends radially outwardly and which may be used by the operator for rotating the cam 122.

A suture channel 130 is provided near the distal end of probe guide 125. Channel 130 cooperates with an annular or

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slotted recess 160 near the distal end of the probe 115. Suture channel 130 comprises an opening in the probe guide 125 which extends radially inwardly into the guide 125 and then generally axially along the guide 125 towards the distal end.

5       The annular or slotted recess 160 in the probe 115 is located such that when the probe 115 is retracted to the proximal limit, the recess 160 and the opening in the channel 130 are aligned for receiving a suture therein.

At least a portion of the suture channel 130 extends 10 generally axially along the guide 125 such that when a suture 165 is located in the recess 160 of the probe 115, the probe 115 may be extended to an intermediate, "locked" position, or to a distal position in which tip 120 is exposed outside of the probe guide 125. In this extended probe position and at 15 all positions between the proximal and distal limits, the suture 165 is trapped within the recess 160 in the probe 115.

As with the drill guide discussed supra, it is preferred that this instrument be manufactured from a sterilizable material having sufficient rigidity for its intended purpose. 20 Many acceptable materials are well known in the art, such as stainless steel for the needle and needle guide, and stainless steel or a plastic for the handle portion.

The suture passer 105 is operated first by rotating the cam 122 that engages the rod 145 and extends the probe end 120 25 distally of the probe guide 125. The passer 105 is then extended into a patient's body by gripping the handle 110 and pushing the free end of the probe guide 125 into the body and through the layers of tissue in the same manner as the Stamey needle discussed in Example I, infra, and illustrated in Figs. 9A-10H. The cam 122 is then released and rotates to its 30 neutral position 148 via action of spring 142 against the body 116 in turn pressing the rod 145 proximally against the cam ramp 149. The probe end 120 is thereby retracted into the probe guide 125 so that the suture passer can be manipulated 35 without injury to surrounding tissue while keeping the suture 165 trapped in channel 130.

The suture passer 105 is then guided as discussed in

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Example I, to the desired capture point (see Fig. 10A) and the cam 122 rotated to a position in which the suture channel 130 is aligned with the recess 160 of the probe 115. A length of suture 165 is introduced at the transvaginally introitus and 5 digitally pressed against the outside of the probe guide 125 at a point proximal to the suture channel opening 130.

The suture 165 is then moved proximally until the suture 165 falls into the channel opening 130 and the annular or slotted recess 160 on the probe 115. The cam 122 is then 10 released so that rod 145 slides down cam ramp 149 under the bias of spring 142. At this time, the suture 165 is held securely within the channel 165, and distal tip 120 is retracted within guide 125. The passer 105 may then be 15 retracted from the body, thus drawing the suture 165 from inside the body. The construction of a bladder neck suspension web utilizing the suture passer will become apparent from the method disclosed in Example I, infra.

### III. SUTURE TENSIONING

In accordance with another aspect of the present invention, a reproducible technique of tying the suspending suture is described. Tying down on something with the approximate dimension of the distal pulp of an index finger leaves a small amount of slack in the suture which permits a controlled and limited suspension of the bladder neck when suspended in this way. The slack is acceptable because of the 20 large volume of pubocervical fascia lending support to the bladder neck. It has been observed to be relatively difficult to place excessive tension on the bladder neck. Chronic urinary retention is avoided by utilizing the suture tensioner disclosed herein, and the chance of acute retention is minimized, thereby promoting a reduction in periods of 25 indwelling and intermittent catheterization.

Chronic retention with endoscopic bladder neck suspension has been reported in as many as 5 to 18.9 percent of patients 30 in other series<sup>11,12</sup>. Excessive tension with overcorrection of the bladder neck is also known to account for bladder instability<sup>13</sup>. In the study by the present inventor, urinary

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urgency and urgency incontinence diminished following surgery with the limitation of suture tension described herein. This reduction in irritative urinary symptoms was also associated with the lateral placement of the pubocervical sutures.

5       The period of hospitalization was reduced within the tension limiting group in the experimentation conducted by the inventor herein. A limit on suture tension may be found, over time, to decrease suture pull through at the pubocervical fascia and, therefore, enhance long term efficacy. The one  
10      failure in the study conducted by the present inventor occurred in a patient who had the suspending suture tied in the prior art tighter and more arbitrary manner.

15      The modifications described herein attempt to further reduce the limitations of the present forms of bladder neck suspension in a select group of patients with SUI (grade 1 and 2). Safety and short term efficacy of the modifications were good. Patient inconvenience in terms of the period of hospitalization and intermittent catheterization was limited. The period of indwelling catheter drainage will be shortened  
20      in the future. Satisfaction in the patient group was high. The priority of improved long term efficacy is stressed in these techniques that allow the accurate and secure placement of suspending sutures in a reproducible manner that minimizes the tensions placed upon those tissues that are suspended.

25      As an alternative to tying down against the index finger, there is provided herein a suture tensioner for providing consistent, repeatable amounts of slack (tension) in the suture sling. As with the use of the index finger described supra, the use of the suture tensioner minimizes post-operative urinary blockage caused by excessive tension, and minimizes post-operative urinary incontinence due to insufficient tension. In addition, the suture tensioner permits the visualization of suture knots during tying, thereby ensuring consistency of alignment and tension of knot  
30      loops.

35      Referring to Figure 7, there is disclosed one embodiment of a suture tensioner in accordance with the present

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invention. The suture tensioner 170 may be constructed in any of a variety of ways which will be well understood by one of skill in the art of constructing medical devices, such as by injection molding or lathing processes.

5       The suture tensioner 170 comprises generally an elongate handle 172 and a body portion 174. The handle 172 may be integrally formed with the body 174, or may be separately produced and affixed such as by insertion into an opening 173 in the body 174, and retained therein such as by threads, 10 adhesives or other conventional means.

The main body 174 comprises a generally cylindrical mass, having a relatively blunt distal end 176 and an annular or semi-annular recess 178 extending about an axis of the main body 174 which is generally perpendicular to the longitudinal axis of handle 172. Other configurations will also become apparent to one of skill in the art in view of the present disclosure.

15       In the illustrated embodiment, the annular recess 178 extends into the main body 174 to a depth of about 0.2 mm, and has a radius of approximately 0.5 mm. These dimensions have been found suitable for tying down the sutures typically utilized in the bladder suspension procedure, which typically have a diameter of about .5 mm. The main body 174 has an axial length of about 15 mm, and a distance between distal end 176 of main body 174 and annular recess 178 of about 8 mm.

20       The handle 172 extends into the main body 174 to a depth of approximately 14 mm, and the remaining exposed handle has a length of approximately 100 mm. The diameter of the main body 174 is approximately 16 mm.

25       As will be apparent to one of skill in the art in view of the foregoing disclosure, any of a wide variety of modifications can be made to the basic dimensions recited herein, and still permit accruing the advantages of this aspect of the present invention.

30       In addition to providing a reproducible amount of slack in the tied suture, the use of suture tensioner 170, spaces the knot tying region apart from the tissue during tying.

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Isolation of the joining region of the suture ends from the tissue facilitates the use of chemical or thermal bonding of suture ends as an alternative to conventional knotting procedures.

For example, opposing lengths of suture can be wrapped part way around the suture tensioner towards each other to provide an overlap zone in which the sutures are held against each other within the groove 178. In the case of suture made from polypropylene or other thermally bondable material, a heat source can be applied to the area of suture overlap to rapidly fuse the two ends together. Excess suture can then be cut and discarded. Depending upon the intensity of the heat source, the suture tensioner 170 may provide sufficient heat capacity to prevent injury to adjacent tissue, or additional heat sink structures or fluid cooling systems can be used. Suitable heat sources include conventional laser and fiber optic systems currently available for cautery and surgical procedures.

Alternatively, adjacent lengths of suture can be bonded by applying a quantity of a solvent or a monomer or other polymerization imitator for initiating a chemical bonding therebetween. Fugative solvent or other agent can be driven from the bonding site by application of heat prior to removal of the suture tensioning tool.

25

#### EXAMPLE I

##### A. Patient History

The records of 30 women with SUI who were treated with modified endoscopic bladder neck suspensions consecutively by the author were reviewed. Twenty-eight patients underwent modified endoscopic bladder neck suspensions alone, while two patients had modified endoscopic bladder neck suspensions with concomitant vaginal procedures such as rectocele and/or cystocele repairs. The patients' ages ranged from 38 to 74. The grading of SUI, based on the Stamey system<sup>2</sup>, was grade 1 in 13 patients and grade 2 in 17 patients. There were no grade 3 patients. Patients had a median of 2 vaginal deliveries. Fifty-seven percent of patients had had a

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previous hysterectomy. Twenty percent of patients had had at least one previous surgical procedure to correct urinary incontinence.

All patients had a history demonstrating bothersome urinary leakage with activities and physical examination demonstrating a hypermobile urethra and pliable pubocervical fascia. Complaints preoperatively included urgency in 63% and urgency incontinence in 40% of patients. Preoperative testing in all patients included 1) a Marshall test that demonstrated leakage with coughing and one finger control of leakage with bladder neck elevation and 2). a cystometrogram that did not demonstrate uninhibited contractions.

B. Technique

All patients received gentamicin and ampicillin preoperatively unless an allergy existed. Anesthesia was regional in 16 patients and general in 14 patients. A surgical assistant was not used. The patients were placed in the lithotomy position. Preparation emphasized isolation of the anus with a stapled towel or plastic drape. A Foley catheter was passed.

Two separated, one inch transverse incisions were made over the pubic bone (Fig. 8) and dissection was carried down to the area of the rectus fascia. Beginning on the right side, the wound was stretched cephalad to allow the vertical passage of a Stamey needle (Pilling Company, Fort Washington, Pennsylvania) through the rectus fascia (Fig. 9A). The needle was then sharply angled onto the abdomen so that the point rested on the underside of the pubic periosteum (Fig. 9B).

The point of the needle, while maintaining contact with the underside of the pubis, was thereafter passed distally toward the introitus. At the completion of this distal passage, the needle could be palpated through the introitus to the right of the urethra (Fig. 9C). Palpation through the vagina was avoided during this distal passage of the needle to avoid pushing the bladder or urethra into the path of the needle. The tip of the needle was withdrawn from the pubourethral ligament and gently swept along the pubocervical

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fascia to the area of the bladder neck (Fig. 9D) under the guidance of a finger within the vagina.

The needle was then passed through the pubocervical fascia and vaginal mucosa at point 1 (Fig. 10A). A number 1 polypropylene suture was passed through the needle hole and withdrawn with the needle through the pubic wound (Fig. 10B). The needle was then reintroduced through the rectus fascia 2 cm. lateral to the initial passage and through the vaginal mucosa at point 2 (Fig. 10C) using the same needle passage technique described above (Fig. 9A-D). The tip of the needle with the vaginal end of the suture was then withdrawn into the retropubic space (Fig. 10D) and then advanced to point 3 where it was passed through the vaginal mucosa and passed distal to the introitus (Fig. 10E).

The suture was then removed from the needle and the needle tip was once again withdrawn to the retropubic space (Fig. 10F) and passed through the vaginal mucosa at point 4 (Fig. 10G). The vaginal end of the suture was then passed into the needle and pulled up through the pubic wound using the needle (Fig. 10H). An attempt was made with the 4 entry points through the pubocervical fascia to maximize 1) their separation (approximately 2 cm. apart), and 2) their lateralization from the bladder neck and urethra (approximately 2 cm. away) (Fig. 13A).

The identical procedure was performed on the left side. Direct or video cystoscopic confirmation of suture position was performed on the left side. Direct or video cystoscopic confirmation of suture position was performed with special attention to avoid handling the contaminated eyepiece of the cystoscope (when video cystoscopy was not done).

The Mitek Anchor System (Mitek Surgical Products, Inc., Northwood, Massachusetts) was then used in all patients for pubic bone fixation of the suspensory sutures. Mitek G1 anchors (Fig. 11A) were used in the first seven patients and the newer Mitek G2 anchors (Fig. 11B) were used in the remaining 23 patients. Two holes were drilled into the pubic bone approximately 2 cm. lateral to the symphysis (Fig. 12A).

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One anchor for each side (2 per patient) was loaded with a medical suture end (which had had less vaginal contact than the lateral ends, thereby, potentially reducing the chance of bacterial contamination). Each anchor was placed into its hole using an inserter (Fig. 12B). The inserter was extracted leaving each anchor in place (Fig. 12C). Traction was placed on the sutures to assure adequate fixation of the anchors.

The sutures on each side were then tied down with sufficient tension so as to develop a gentle elevation and cradle-like support of the bladder neck (Fig. 13A and 13B). A modification to limit and control the tension on the suspending suture web in a reproducible manner was instituted in the last 17 patients within the study. The sutures in these patients were tied down snugly on the distal pulp of the index finger (Fig. 14).

The wounds were irrigated with a bacitracin solution. The wound edges and the rectus fascia at the suture entry points were infiltrated with bupivacaine. A Foley catheter was placed in 80% of the patients. The remaining patients had a suprapubic tube placed because of the dexterity problems or their aversion to learning intermittent catheterization.

Following surgery, patients were given either ciprofloxacin or ofloxacin for 10 days. The patients' Foley catheters were removed one week following surgery. The patients performed intermittent catheterization as necessary until the post-void residuals were less than 75 cc. on two consecutive catheterization. Patients with suprapubic tubes generally began voiding trials at 4 days following surgery. The suprapubic tubes were removed when the post-void residuals were less than 75 cc. following two consecutive urinations.

#### C. Results

All 30 women who underwent this procedure were evaluated within the first month post-operatively ("post-op" follow-up). The initial 16 consecutive patients of this group were evaluated up to eight months after surgery by mail questionnaires ("short-term" follow-up). Three patients who did not return their questionnaires were contacted by phone.

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The procedure was performed on an outpatient basis in 12 of the last 17 patients with the suture tension limiting technique (71%) compared to 2 of the first 13 patients without the technique (15%) (Fig. 15). Many patients did not require narcotic analgesics following discharge. Seventy-three percent of patients did not require intermittent catheterization beyond the day that their indwelling catheter was removed (Fig. 16). All patients became catheter free. The prevalence of urinary urgency was similar at the post-op and short term follow-ups at 17 and 19 percent, respective (Fig. 17). Six percent of patients complained of urgency incontinence on short term follow-up. Twenty-nine of 30 patients (97%) had cure of stress incontinence on follow-up; all 30 patients on post-op follow-up and 15 of 16 (94%) on short-term follow-up. Cure was defined as the lack of urinary leakage with activity. One woman developed urinary leakage three months following her surgery. She had the first set of G1 anchors placed and also had the suspending suture tied without the technique of tension limitation. That patient's anchors appeared to be within the pubic bone on an anterior-posterior view of the pelvis. Figure 18 indicates the patients' satisfaction with the results of their procedure as taken from their short term questionnaire. There were no wound or bone infections.

25

#### EXAMPLE II

A group of patients are prepared in the manner described in Example I. Two separated, one inch transverse incisions are made over the pubic bone (Fig. 8) and dissection is carried down to the area of the rectus fascia. Beginning on the right side, the wound is stretched cephalad to allow the vertical passage of a suture passer of the type illustrated in Figs. 5 and 6 through the rectus fascia with the probe tip fully exposed (Fig. 9A). Distal advancement of the suture passer is accomplished with the needle (probe) tip proximally retracted within the probe guide. The suture passer is acutely angled into the abdomen so that the point rests on the underside of the pubic periosteum (Fig. 9B).

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While maintaining contact with the underside of the pubis, the suture passer with the probe tip retracted is thereafter passed distally toward the introitus. At the completion of this distal passage, the suture passer can be 5 palpated through the introitus to the right of the urethra (Fig. 9C). The distal end tip of the suture passer is withdrawn from the surface of pubourethral ligament and gently swept along the pubocervical fascia to the area of the bladder neck (Fig. 9D) under the guidance of a finger within the 10 vagina. Palpation through the vagina may be safely preformed to assist in localization of suture passer tip.

The probe tip is then distally extended. The suture passer is then passed through the pubocervical fascia and vaginal mucosa at point 1 (Fig. 10A). The probe is then 15 retracted maximally to the unlocked position to allow a number 1 polypropylene suture to be manually placed into the suture channel. The probe is moved distally to lock the suture therein. The suture passer is thereafter withdrawn through the pubic wound (Fig. 10B) and the suture is released from the 20 suture channel by manually retracting the probe.

The suture passer with the probe tip extended is then reintroduced through the rectus fascia 2 cm. lateral to the initial passage and through the vaginal mucosa at point 2 (Fig. 10C) using the same passage technique described above 25 (Fig. 9A-D). The vaginal end of the suture is then placed into the open end of the suture channel and locked. The suture passer is then withdrawn into the retropubic space (Fig. 10D) and then advanced to point 3 where it is passed through the vaginal mucosa as with point 1 and 2 and passed 30 out of to the introitus (Fig. 10E).

The suture is then removed from the suture passer by 35 maximally retracting the probe tip to the "unlocked" position to align the suture channel and opening in the probe guide, and the suture passer is once again withdrawn into the retropubic space (Fig. 10F). The probe tip is then extended and the suture passer is pushed through the vaginal mucosa at

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point 4 (Fig. 10G). The vaginal end of the suture is then placed into the unlocked suture channel and locked into place, and pulled up through the pubic wound. An attempt is made with the 4 entry points through the pubocervical fascia to maximize 1) their separation (approximately 2 cm. apart), and 5 2) their lateralization from the bladder neck and urethra (approximately 2 cm. away) (Fig. 6A).

The identical procedure is performed on the left side. Direct or video cystoscopic confirmation of suture position is 10 performed on the left side. Direct or video cystoscopic confirmation of suture position is performed with special attention to avoid handling the contaminated eyepiece of the cystoscope (when video cystoscopy is not done).

The Mitek G2 Anchor System (Mitek Surgical Products, Inc., Northwood, Massachusetts) is then used in all patients 15 for pubic bone fixation of the suspensory sutures. Drill sites are located by placing a drill guide 25 illustrated in Fig. 1 over the pubic bone and extending the bone probes distally until both bone probes have made contact with the 20 pubic bone. A 2.5 mm drill bit is advanced through the drill guide to produce two holes drilled into the pubic bone approximately 2 cm. lateral to the symphysis (Fig. 5A). One anchor for each side (2 per patient) is loaded into the drill 25 guide channel and advanced into its hole before removing the drill guide after drilling. Traction is placed on the sutures to assure adequate fixation of the anchors.

The sutures on each side are then tied down with sufficient tension so as to develop a gentle elevation and cradle-like support of the bladder neck (Fig. 6A and 6B). Tension is regulated by tying the sutures across a suture 30 tensioner as illustrated in Fig. 7, and thereafter removing the tensioner.

The patients are thereafter postoperatively treated as described in Example I.

35 Although this invention has been described in terms of certain preferred embodiments, other embodiments that are

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apparent to those of ordinary skill in the art in view of the foregoing are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by reference to the appended claims.

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**REFERENCES**

- 1<sup>st</sup>Pereyra, A.J.: A simplified surgical procedure for the correction of stress incontinence in women. West. J. Surg., 67:223, 1959.
- 5 2<sup>nd</sup>Stamey, T.A.: Endoscopic Suspension of the vesical neck for urinary incontinence in females: Report on 203 consecutive patients. Ann. Surg., 192:465, 1980.
- 10 3<sup>rd</sup>Raz, S.: Modified bladder neck suspension for female stress incontinence. Urology, 17:82, 1981.
- 15 4<sup>th</sup>Leach, G.E.: Bone fixation technique for transvaginal needle suspension. Urology, 31:388, 1988.
- 5<sup>th</sup>Gittes, R.F. and Loughlin, K.R.: No-incision pubovaginal suspension for stress incontinence. J. Urol. 138:568, 1987.
- 15 6<sup>th</sup>Winter, C.C.: Peripubic urethropexy for urinary stress incontinence in women. Urology, 20:408, 1982.
- 20 7<sup>th</sup>McKiel, C.F., Jr., Graf, E.C. and Callahan, D.H.: Marshall-Marchetti procedure: modification. J. Urol., 96:737, 1966.
- 25 8<sup>th</sup>Hancock, R., Brandstetter, L.H. and Hodgins, T.E.: Transpubic suspension of the bladder neck for urinary incontinence. J. Urol., 123:667, 1980.
- 9<sup>th</sup>Richmond, J.C., Donaldson, W.R., Fu, F. and Harner, C.D.: Modification of the Bankart reconstruction with a suture anchor: report of a new technique. Am. J. Sports Med., 19:343, 1991.
- 30 10<sup>th</sup>Pederson, B., Tesoro, D., Wertheimer, S.J. and Coraci, M.: Mitek anchor system: a new technique for tenodesis and ligamentous repair of the foot and ankle. J. Foot Surg., 30:48, 1991.
- 35 11<sup>th</sup>Spencer, J.R., O'Conor, V.J. and Schaeffer, A.J.: A comparison of endoscopic suspension of the vesical neck with suprapubic vesicourethropexy for treatment of stress urinary incontinence. J. Urol., 137:411, 1987.
- 12<sup>th</sup>Araki, T., Takamoto, H., Hara, T., Jujimoto, H., Yoshida, M. and Katayama, Y.: The loop loosening procedure for

-33-

urination difficulties after Stamey suspension of the vesical neck. J. Urol., 144: 1990.

<sup>13</sup>Webster, G.D. and Kreder, K.J.: Voiding dysfunction following cystourethropexy: Its evaluation and management. J. Urol., 144:1990.  
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I CLAIM:

1. A drill guide for directing a drill bit at a selected site, comprising:
  - a housing;
  - 5 at least two probes on the housing; and
  - a drill guide channel extending through the housing, wherein the drill guide channel lies on a plane which extends in between the two probes.
- 10 2. A drill guide as in Claim 1, wherein at least a first one of said probes is axially movable from a first proximal position to a second distal position.
- 15 3. A drill guide as in Claim 2, wherein the distal tip of the first probe is shielded within the housing when the probe is in the first position, and the distal tip of the first probe is exposed outside of the housing when the probe is in the second position.
- 20 4. A drill guide as in Claim 2, wherein at least two of said probes are axially movable between a first proximal position and a second distal position.
- 25 5. A drill guide as in Claim 1, further comprising an actuator for moving the first probe between the first and second positions.
6. A drill guide as in Claim 1, wherein the longitudinal axis of the drill guide channel is approximately equidistant from the longitudinal axes of each of the probes.
- 30 7. A drill guide as in Claim 2, further comprising a drill bushing extending through the drill guide channel.
8. A drill guide as in Claim 1, wherein said probe comprises an elongate solid wire.
- 35 9. A drill guide as in Claim 1, wherein said probe comprises an elongate hollow tube.
10. A drill guide as in Claim 1, further comprising two chambers extending axially within said housing, each of said chambers having an open distal end, and wherein a plunger is located in each of said chambers, each of said plungers being axially movable from a first retracted position to a second extended position, and wherein one of said probes is located

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on the distal end of each of said plungers.

11. A drill guide as in Claim 10, further comprising a releasable lock for releasably retaining at least one plunger in the retracted position.

5 12. A drill guide as in Claim 10, wherein the first probe and the second probe are separated by a distance of within the range of from about .05 to about 1.5 cm.

10 13. A drill guide as in Claim 10, wherein the axis of the drill guide channel is in a plane extending between the axis of each of the probes.

14. A drill guide as in Claim 10, further comprising an axially extending slot in the wall of the drill guide channel for receiving a suture therethrough.

15 15. A drill guide as in Claim 10, further comprising a textured tissue contacting surface adjacent the distal end of the drill guide channel, for resisting the migration of tissue into the drill bore.

16. A method of positioning a drill guide over a drilling site on a bone, comprising the steps of:

20 providing a drill guide of the type comprising a housing, at least two axially extendable probes within the housing and a drill guide extending through the housing;

25 extending a first probe from the retracted position to the extended position;

advancing the first probe through tissue until it contact a bone;

30 extending a second probe from the retracted position to the extended position until said second probe contacts bone; and

35 if either one of the probes does not contact the bone, retracting that probe from the extended position to the retracted position, and translating the drill guide along the superior/inferior axis, and then reextending that probe from the retracted position to the extended position until it contacts the bone.

17. A method of installing a bone anchor in a bone,

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comprising the steps of:

providing a drill guide of the type defined in Claim

1;

advancing each of said probes through tissue until  
each of said probes contacts the bone;

5

advancing a drill bit through the drill guide  
channel and drilling a hole in the bone;

10 withdrawing the drill bit from the drill guide  
channel; and thereafter

10

advancing a suture anchor through the drill guide  
channel and into the bone.

18. A suture passer of the type adapted for releasably  
retaining a suture, comprising:

15

a handle;  
an elongate tubular probe guide extending in a  
distal direction from the handle;

an elongate pointed probe axially movably disposed  
within the tubular probe guide to facilitate penetration  
of tissue; and

20

a recess on the probe and an opening on the tubular  
probe guide for receiving a suture, wherein the probe is  
axially movable with respect to the probe guide between  
a first position in which the annular recess is aligned  
with the opening for receiving a suture therein, and a  
second position wherein the annular recess is out of  
alignment with the opening to trap a suture within the  
recess.

25

19. A suture passer as in Claim 18, further comprising  
a third position so that in a first position the recess is  
aligned with the opening for receiving a suture and the distal  
tip of the probe is retracted within the probe guide; in a  
second position the recess is out of alignment with the  
opening and the distal tip of the probe is retracted; and in  
a third position the recess is out of alignment with the  
opening and the distal tip of the probe is exposed.

30

35 20. A suture passer as in Claim 18, wherein said recess  
comprises an annular or slotted recess extending radially

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inwardly about the periphery of the probe.

21. A suture passer as in Claim 18, further comprising a spring for biasing the probe in the proximal direction.

22. A suture passer as in Claim 19, further comprising  
5 a control on the handle for selectively positioning the probe in any desired one of the three positions.

23. A suture passer as in Claim 18, wherein the distal end of the probe guide is provided with a bluntatraumatic tip which allows tactile positioning digitally.

10 24. A suture passer is in Claim 22, further comprising an axially movable actuator pin extending proximally from the probe.

15 25. A suture passer as in Claim 24, wherein the control comprises rotatable cam having a contoured engagement surface for engaging the actuator pin and holds actuator pin in a stable position.

20 26. A suture passer as in Claim 25, wherein the engagement surface comprises a ramp which cooperates with the actuator pin and the proximal bias on the probe so that the distal tip of the probe is normally retracted within the distal end of the probe guide, and distally extended beyond the probe guide only during manual manipulation of the control.

25 27. A suture passer as in Claim 26, further comprising an indicium on the control for indicating the axial position of the probe.

28. A suture passer as in Claim 27, wherein the indicium comprises the rotational position of the cam.

FIG. I

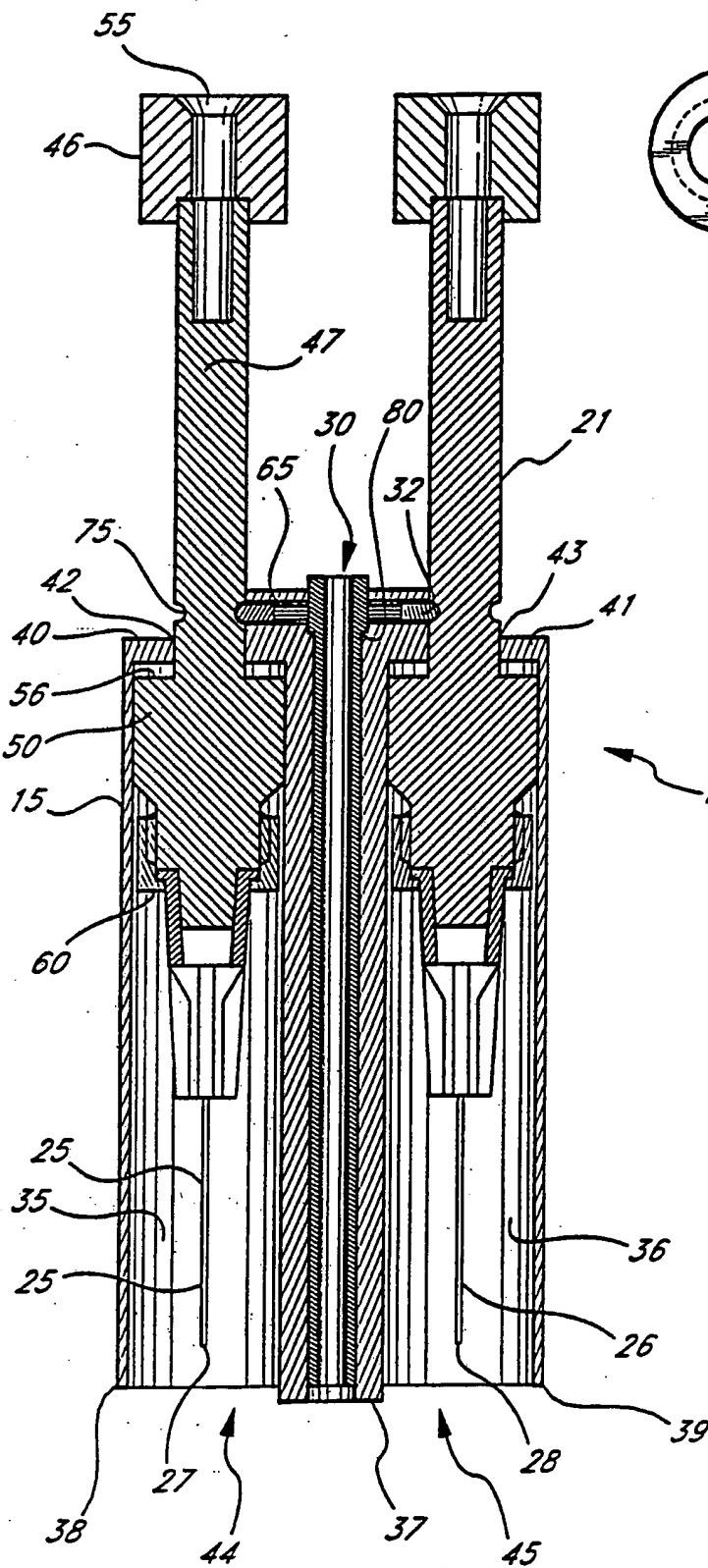
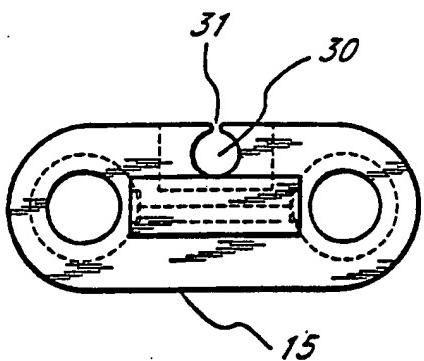
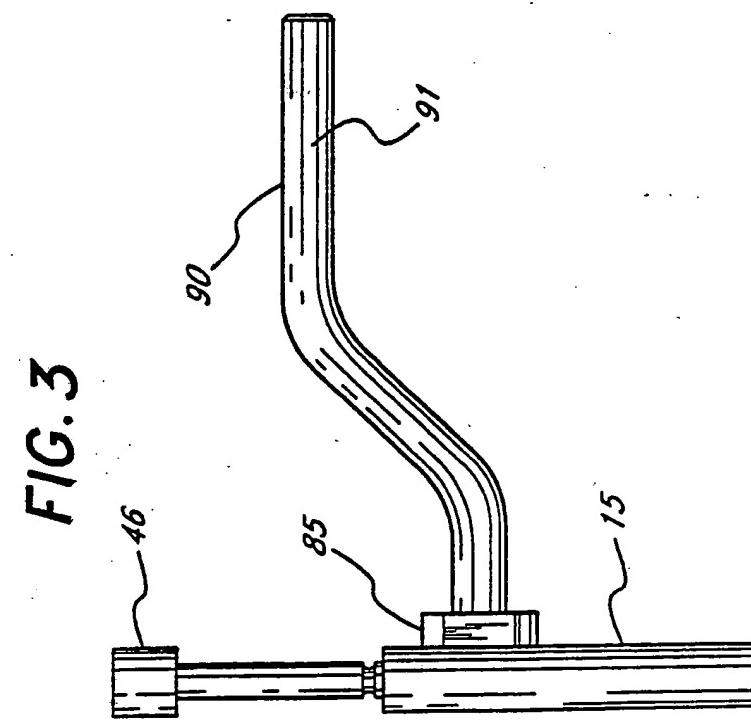
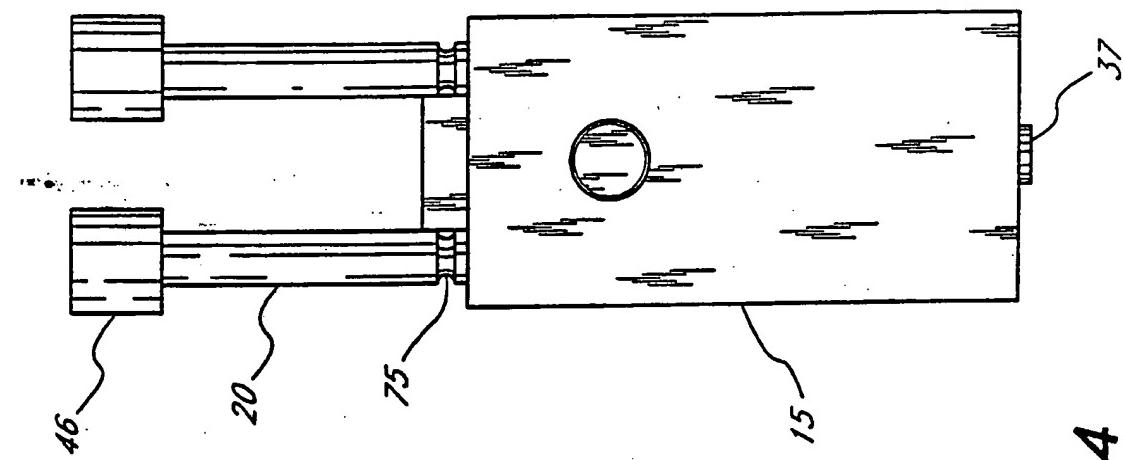


FIG. 2



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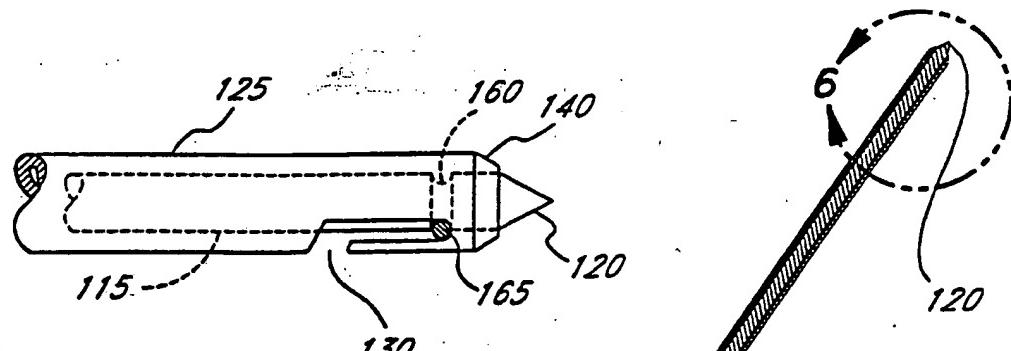
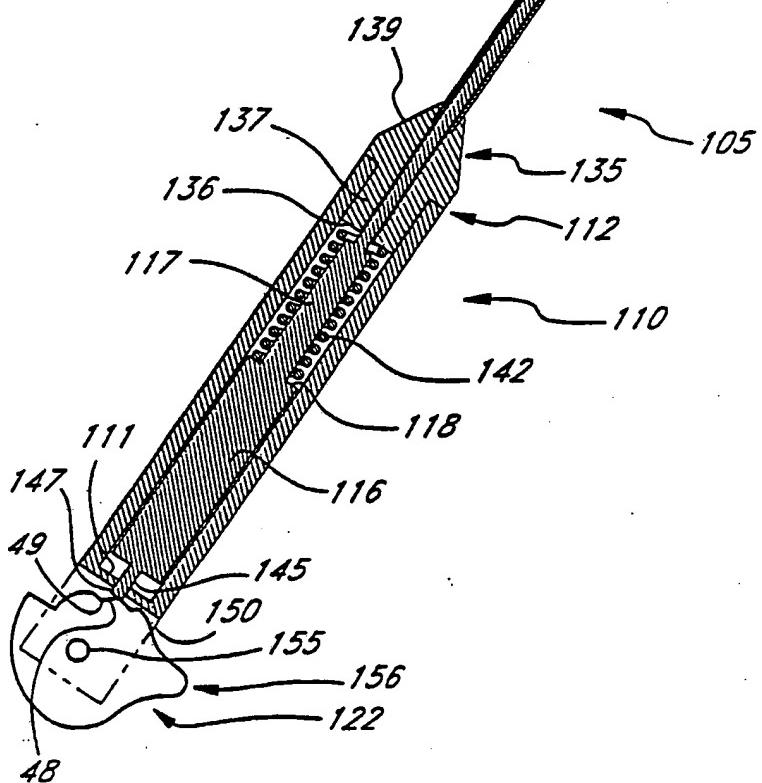


FIG. 6

FIG. 5



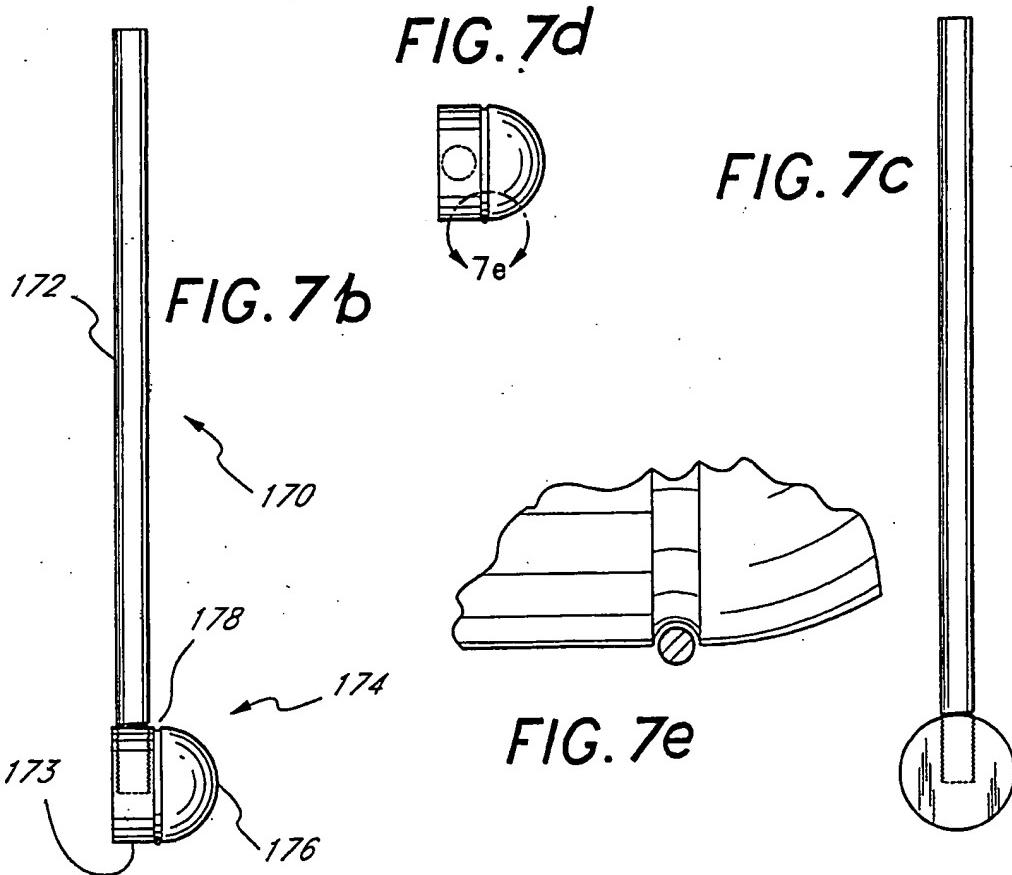
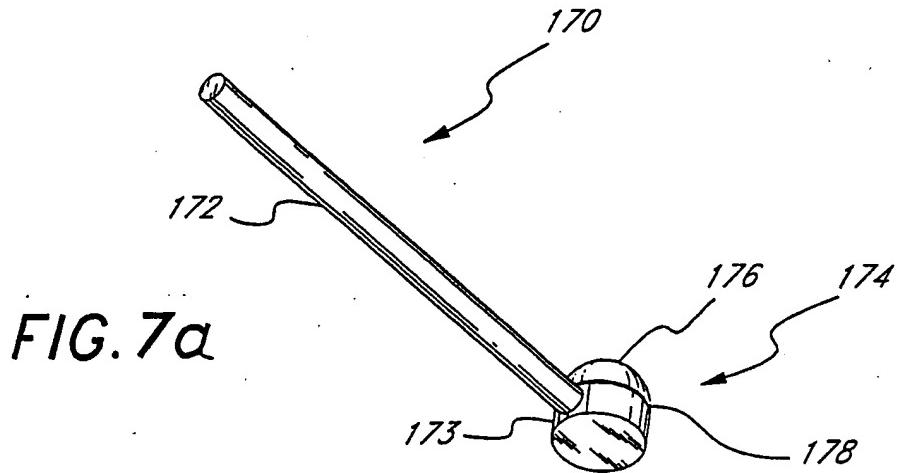
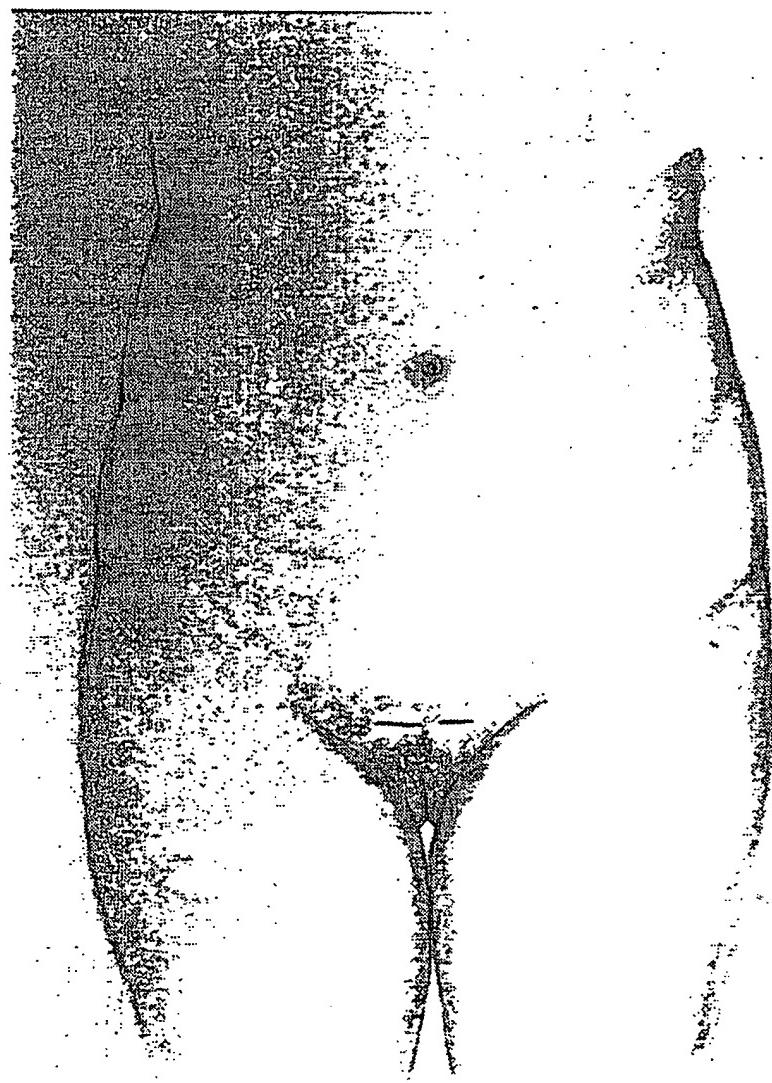
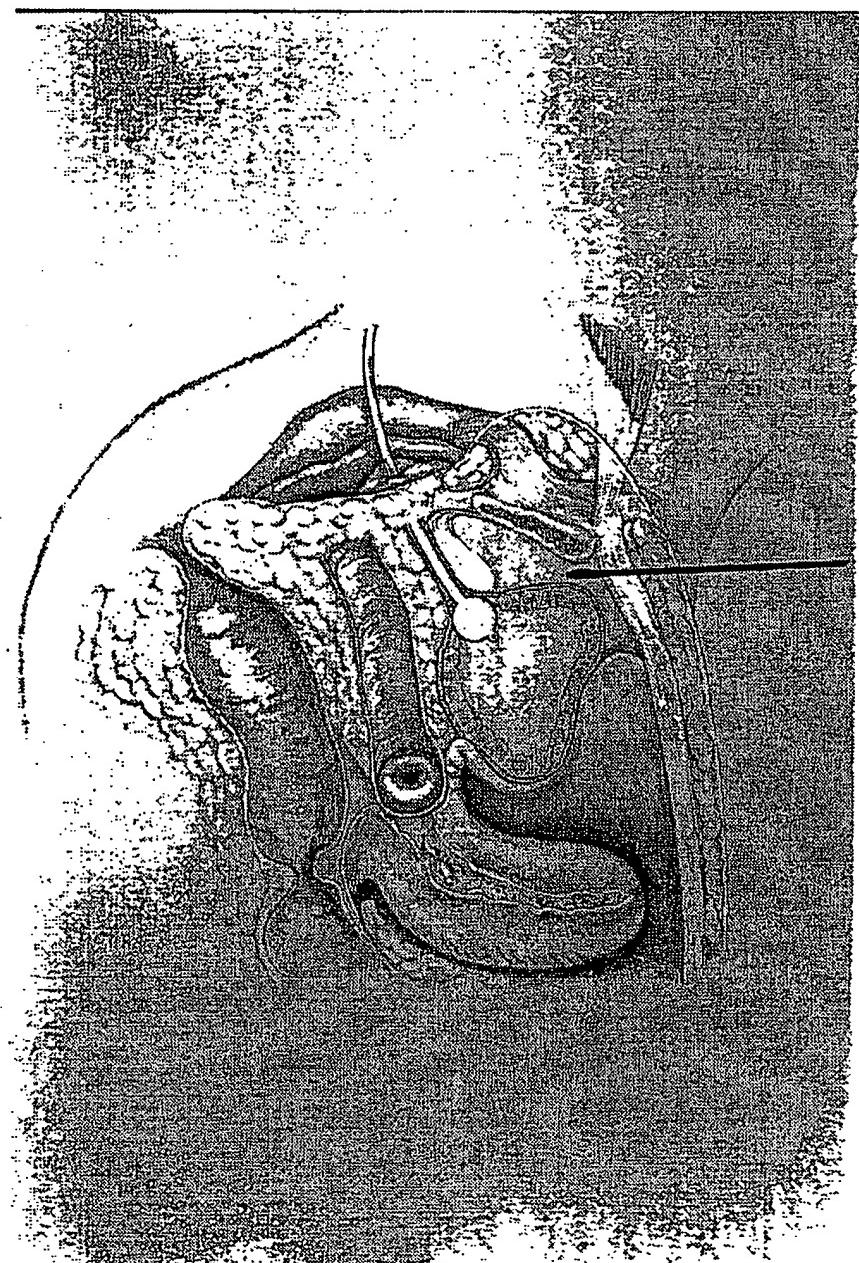


FIGURE 8



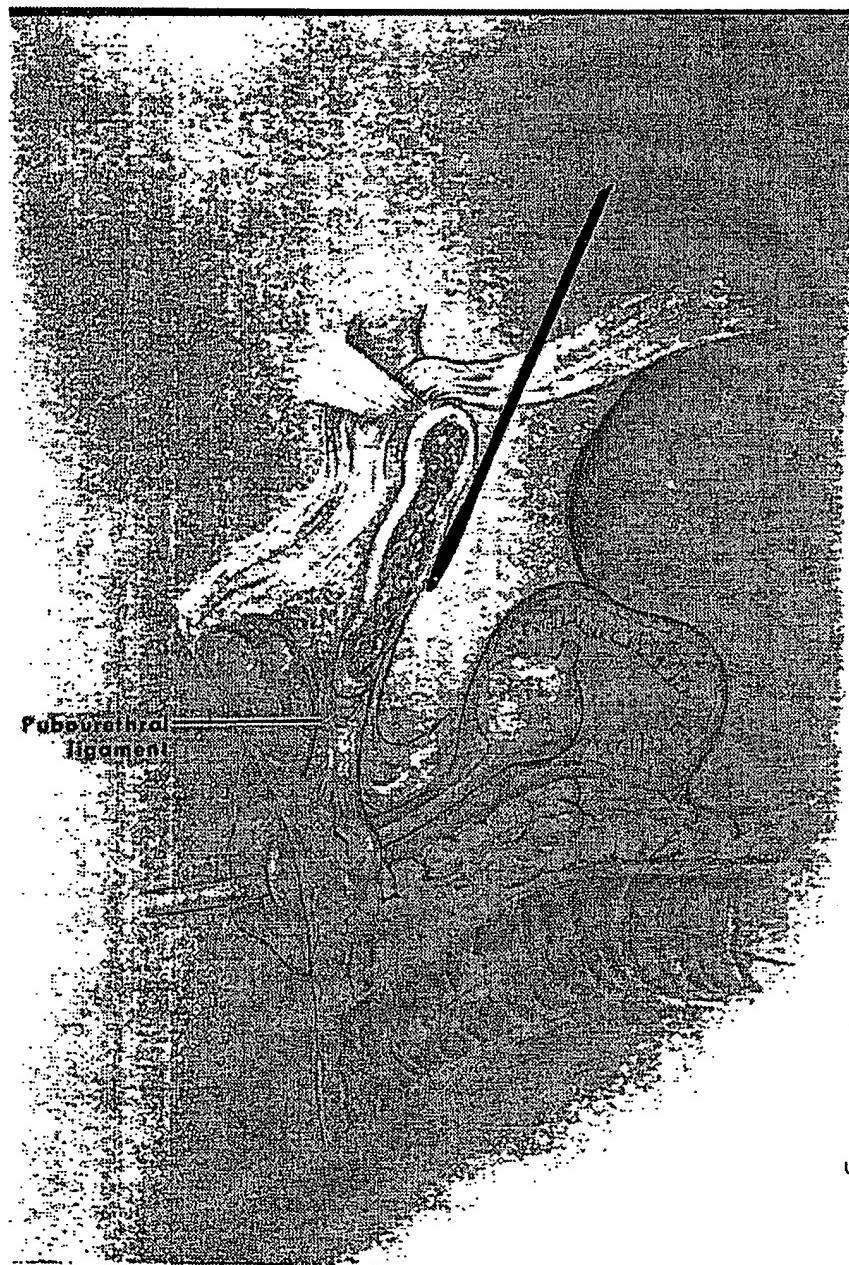
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FIGURE 9A



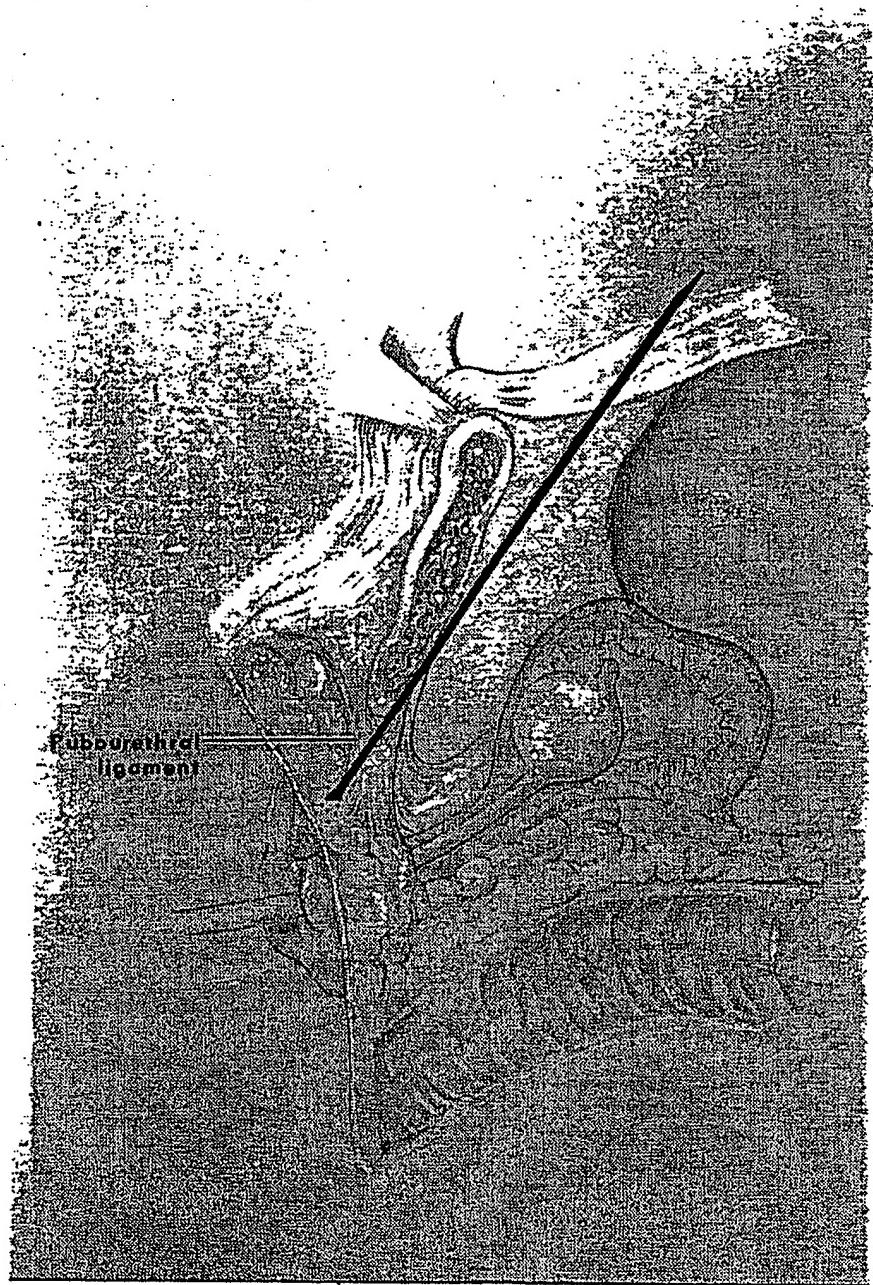
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FIGURE 9B



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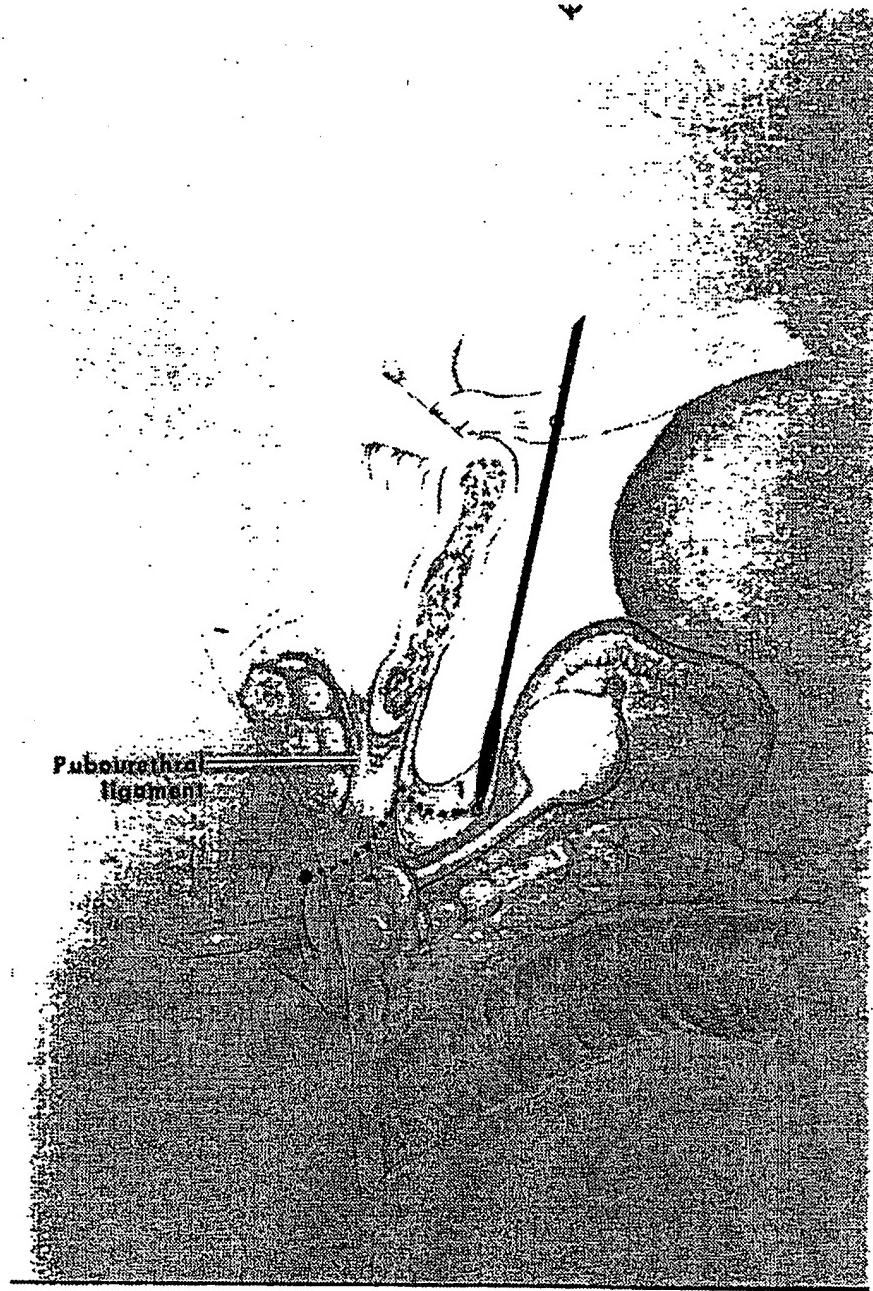
FIGURE 9C



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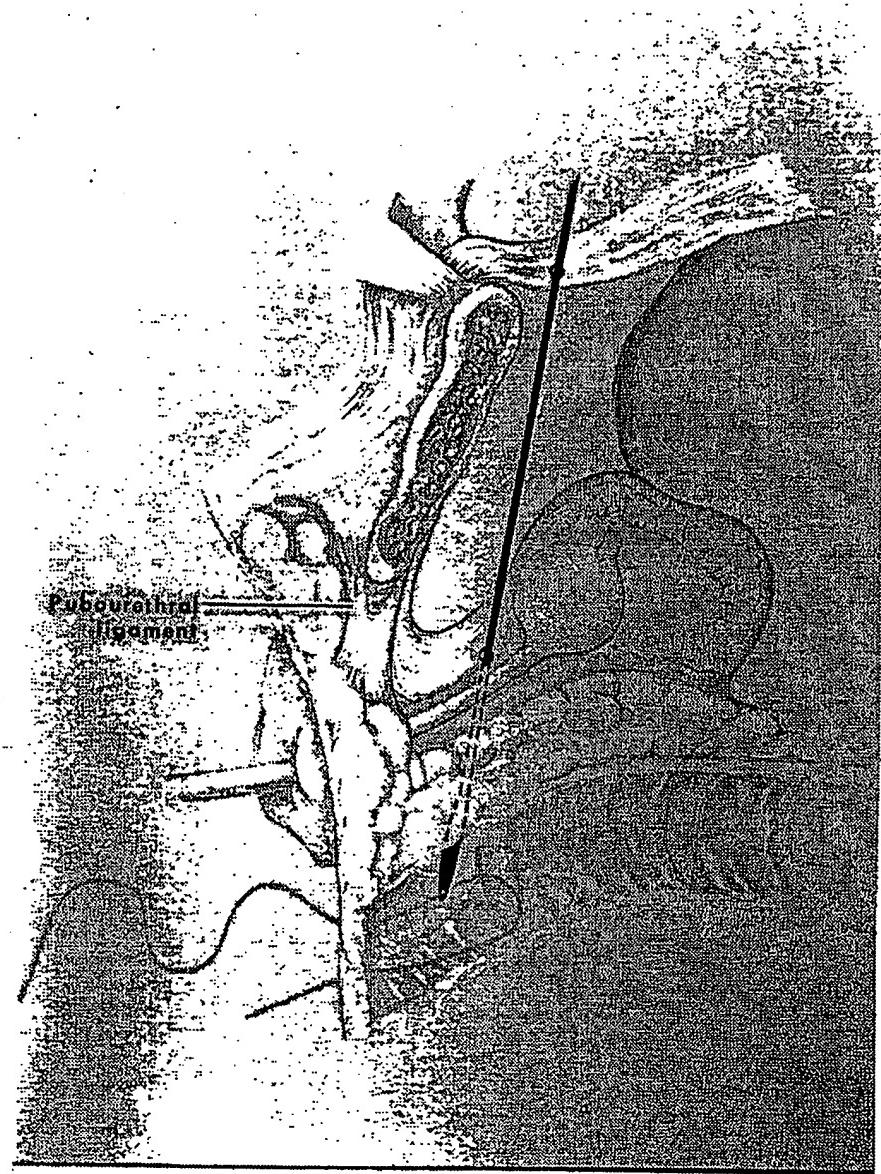
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FIGURE 9D



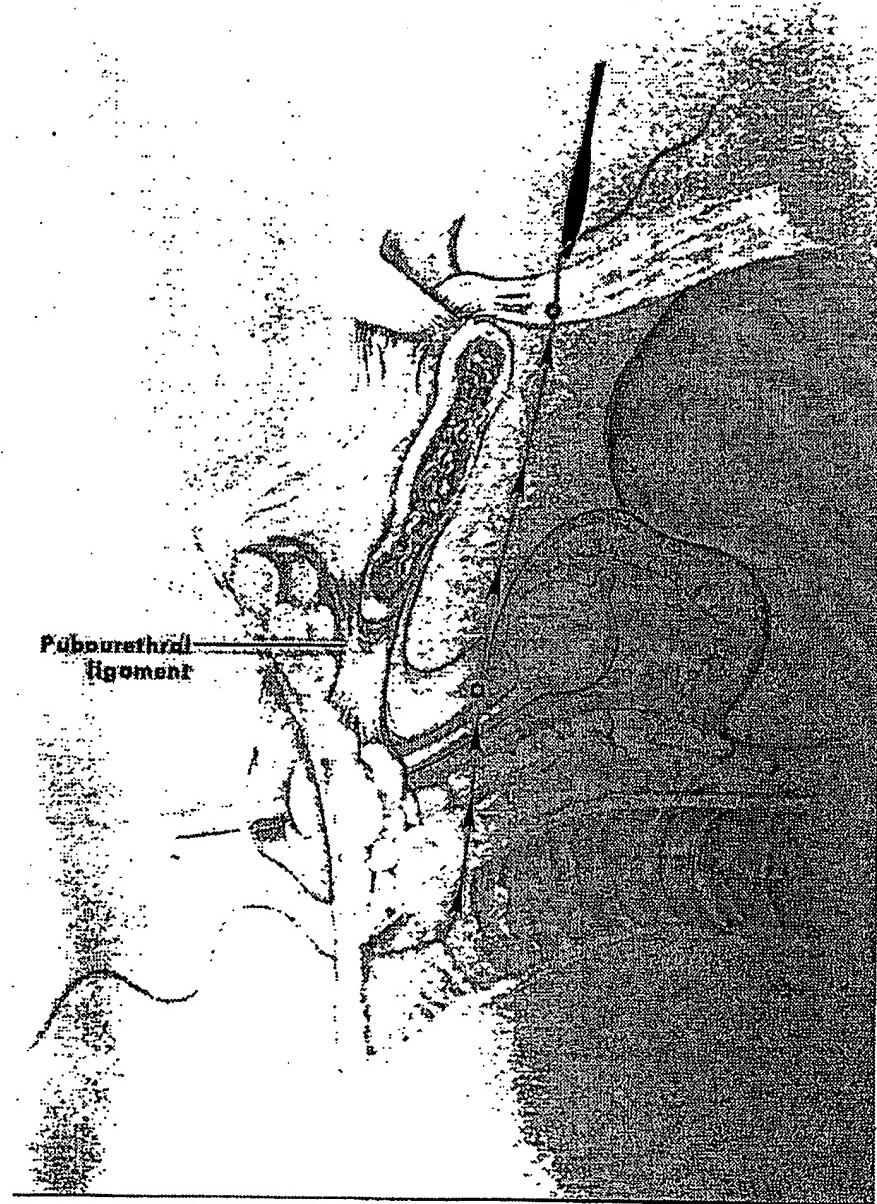
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FIGURE 10A



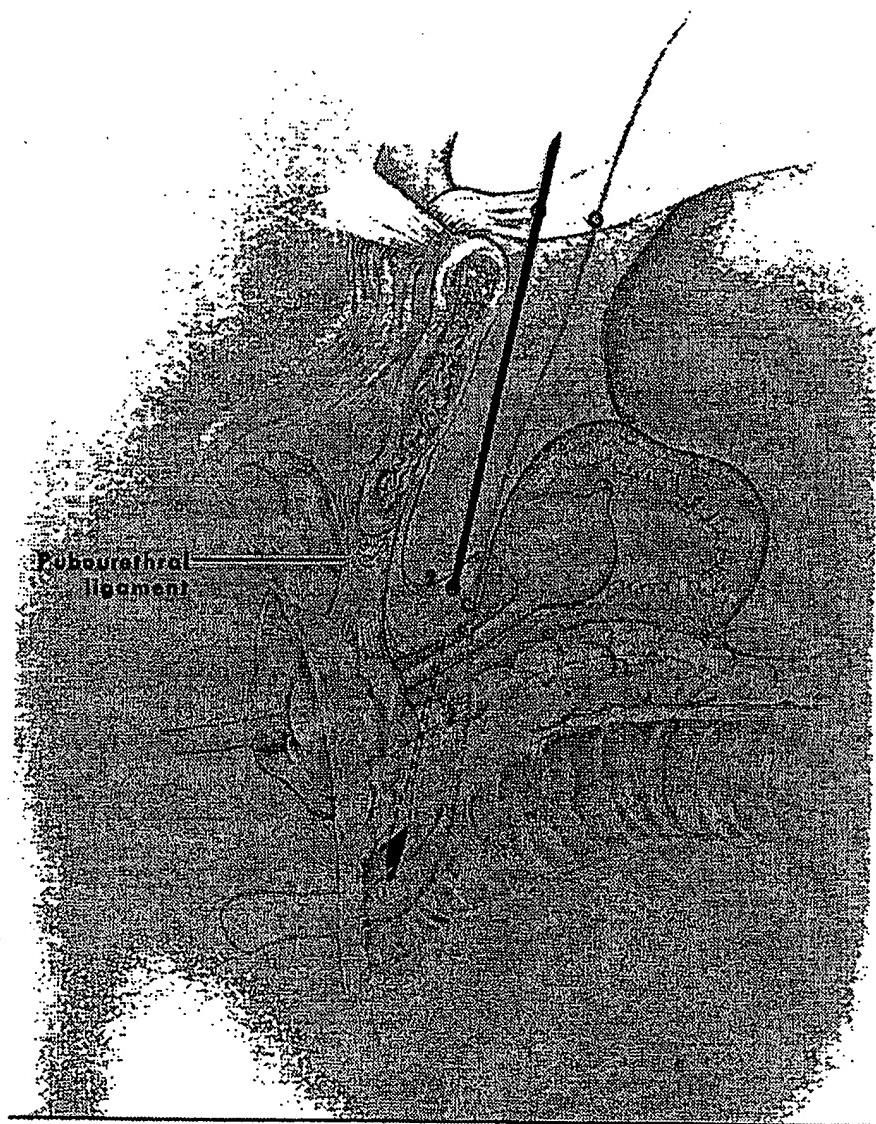
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FIGURE 10B



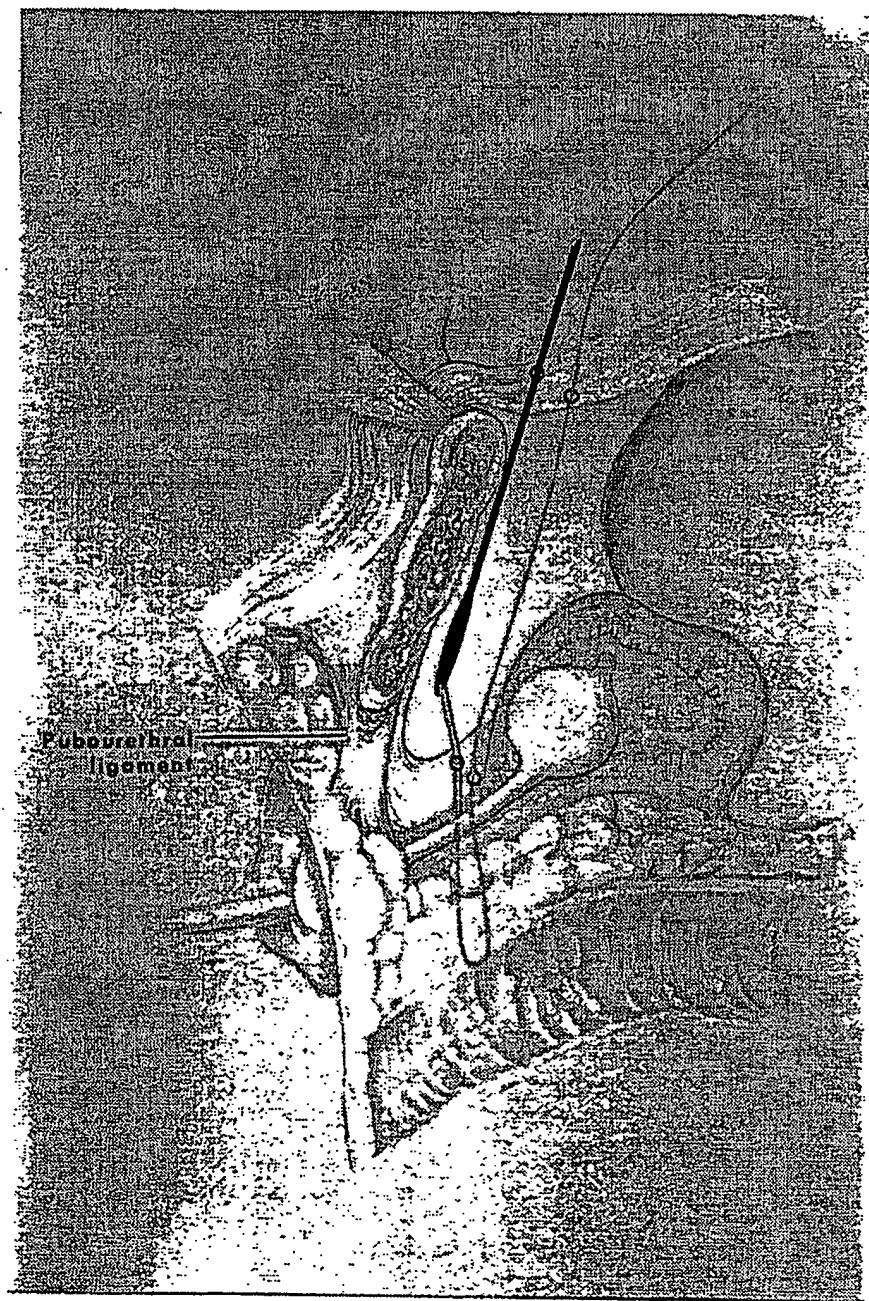
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FIGURE 10C



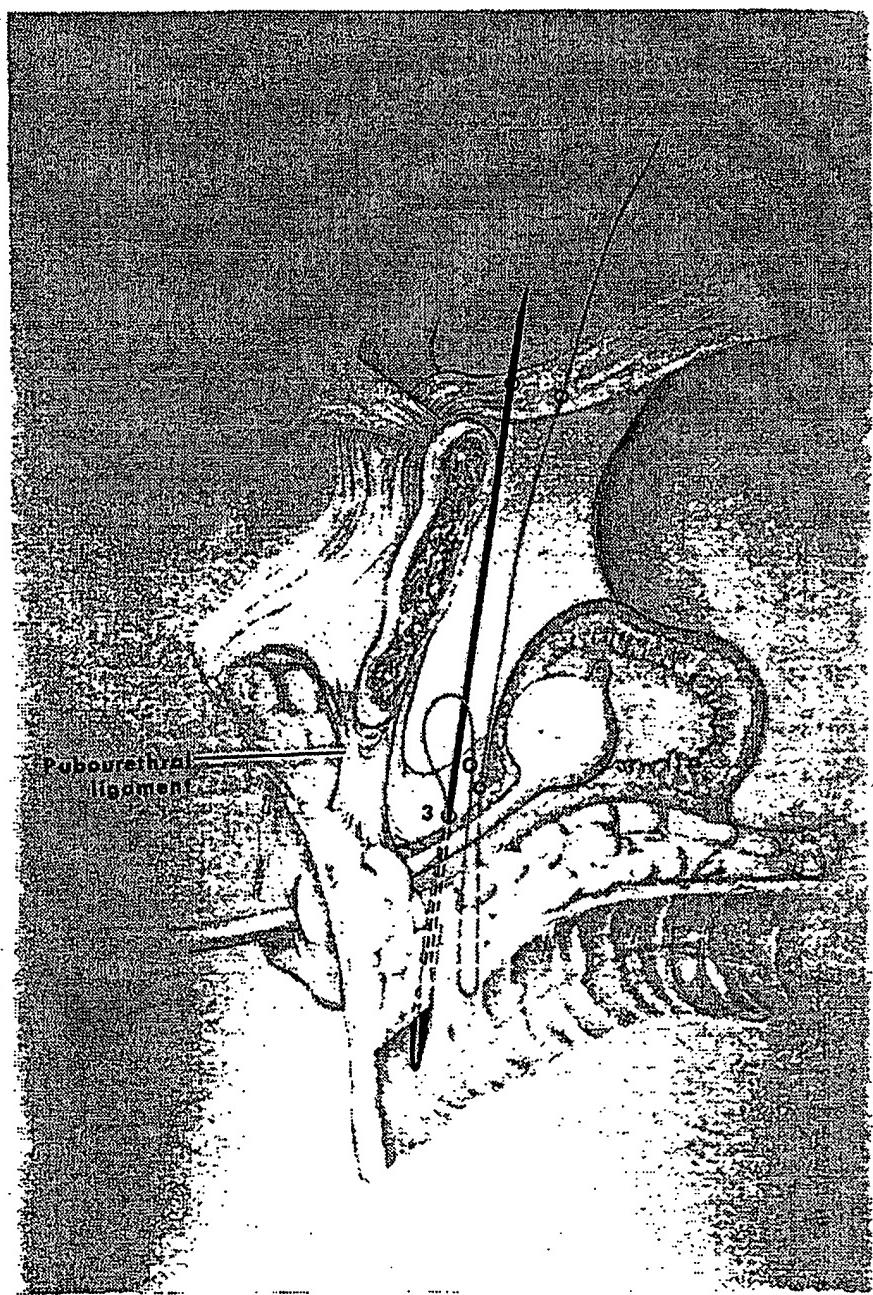
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FIGURE 10D



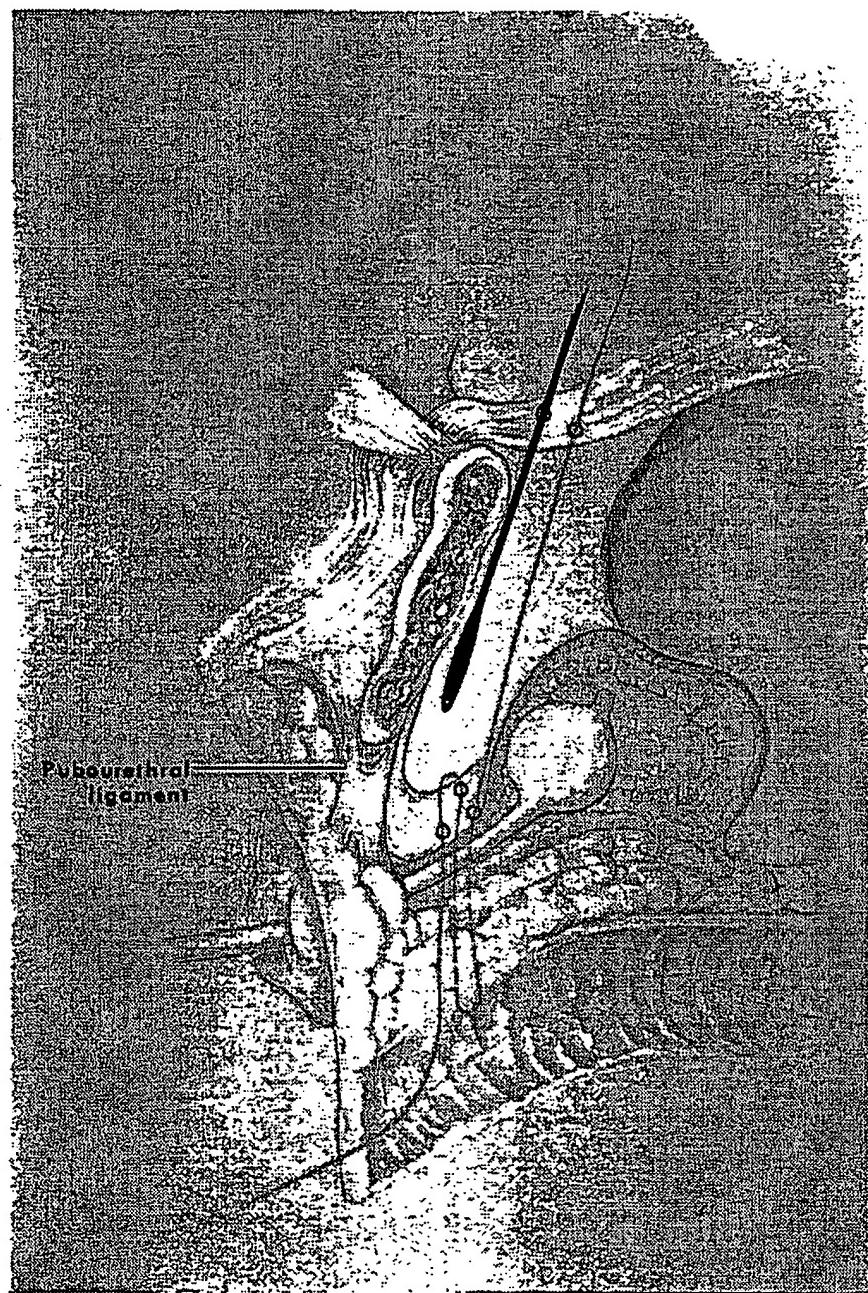
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FIGURE 10E



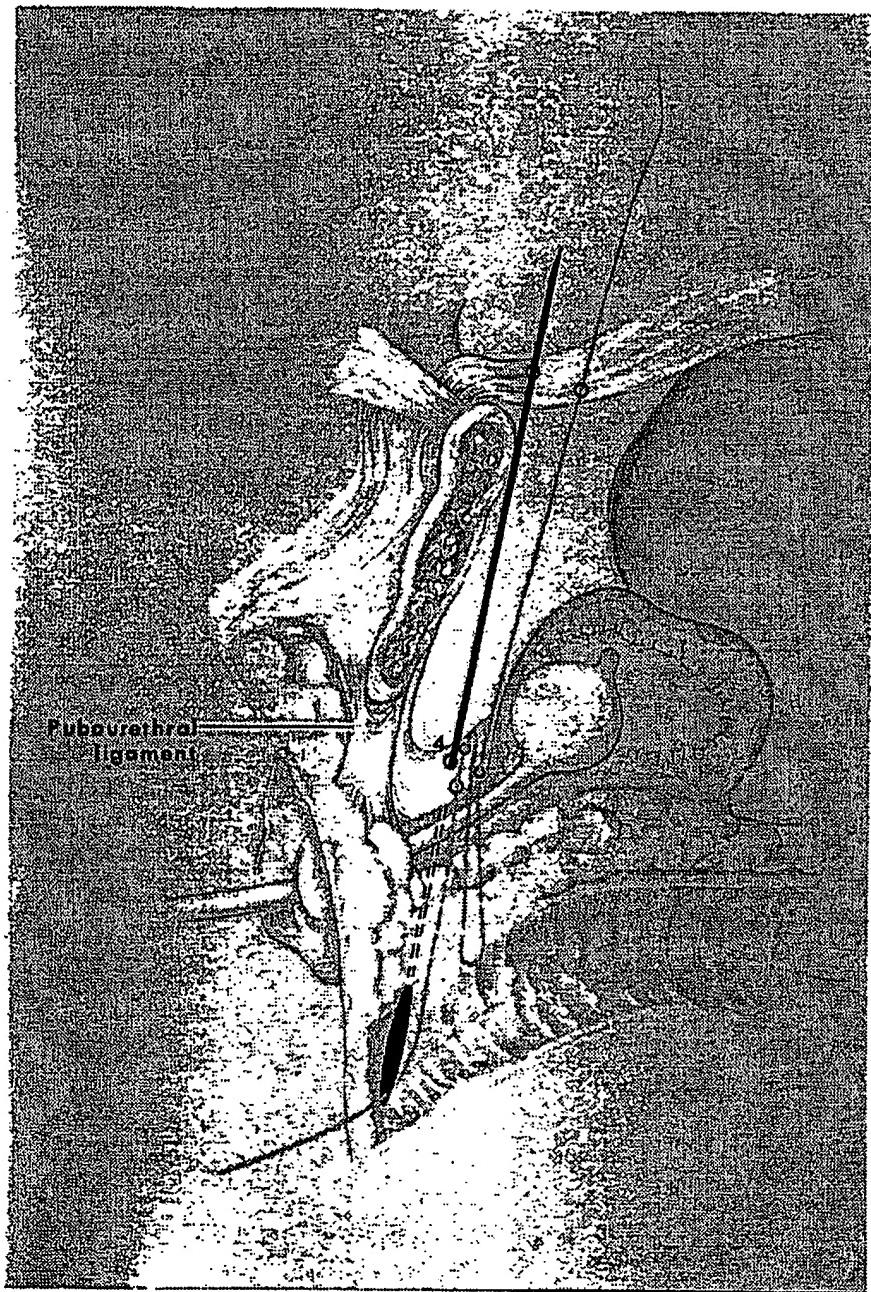
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FIGURE 10F



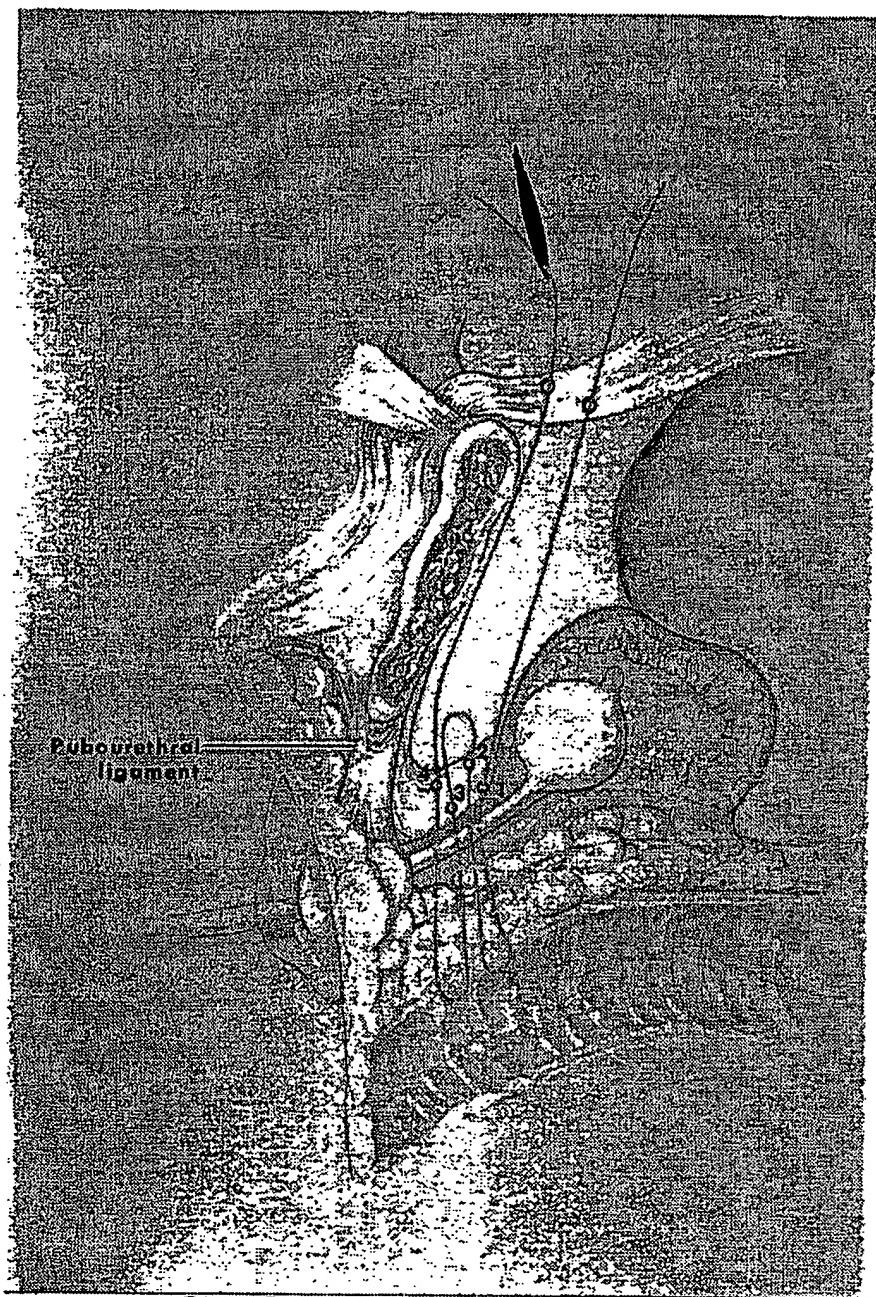
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FIGURE 10G



**SUBSTITUTE SHEET**

FIGURE 10H



**SUBSTITUTE SHEET**

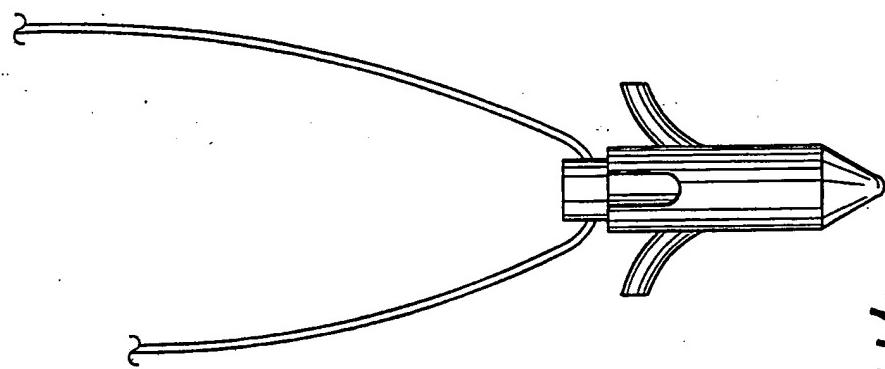


FIG. II b

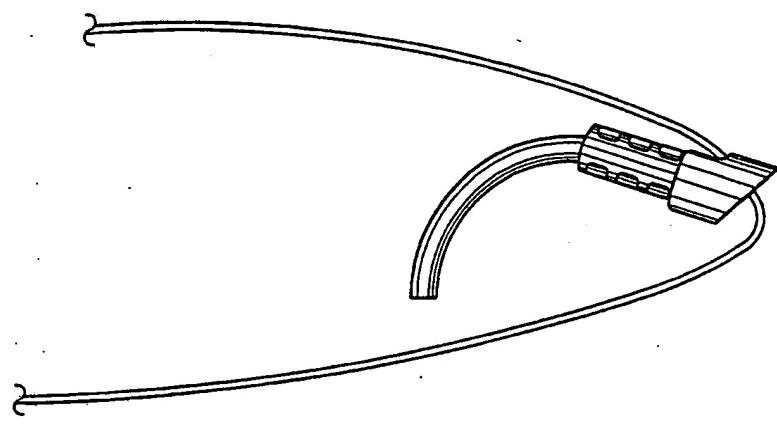


FIG. II a

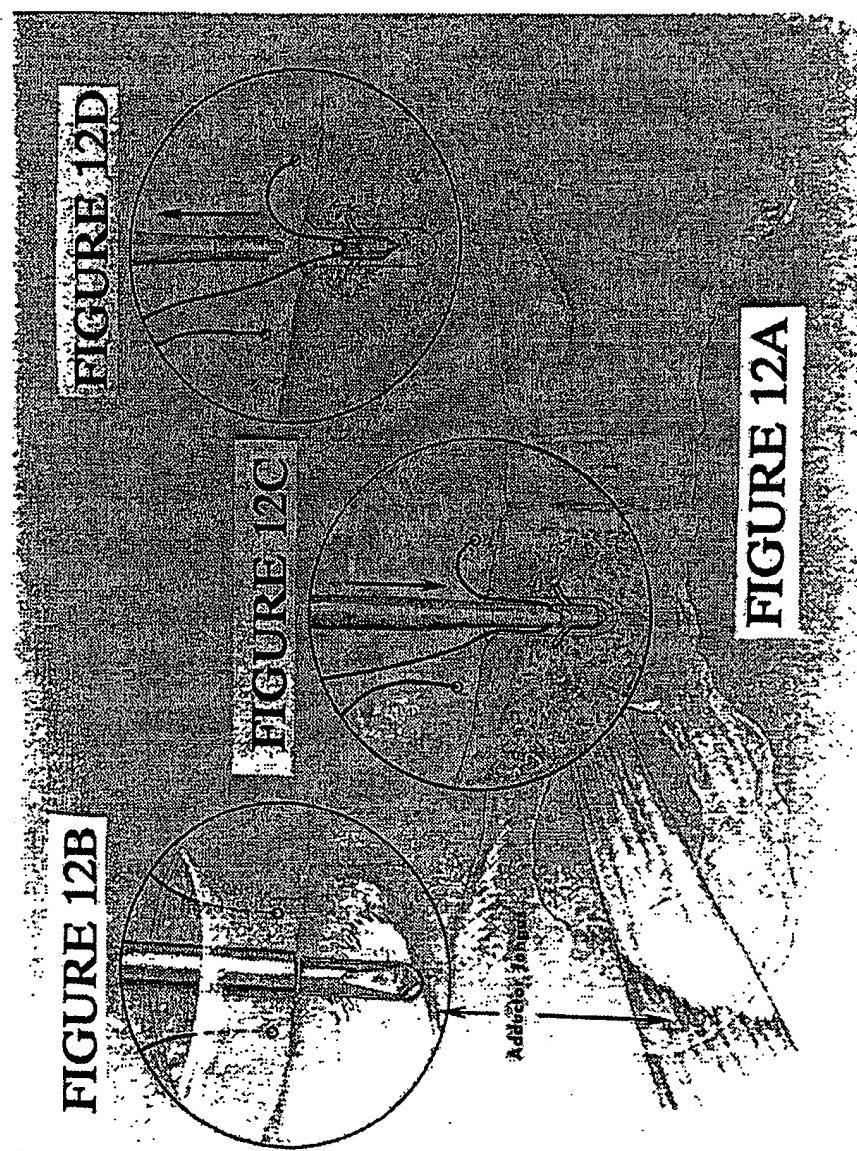


FIGURE 13A



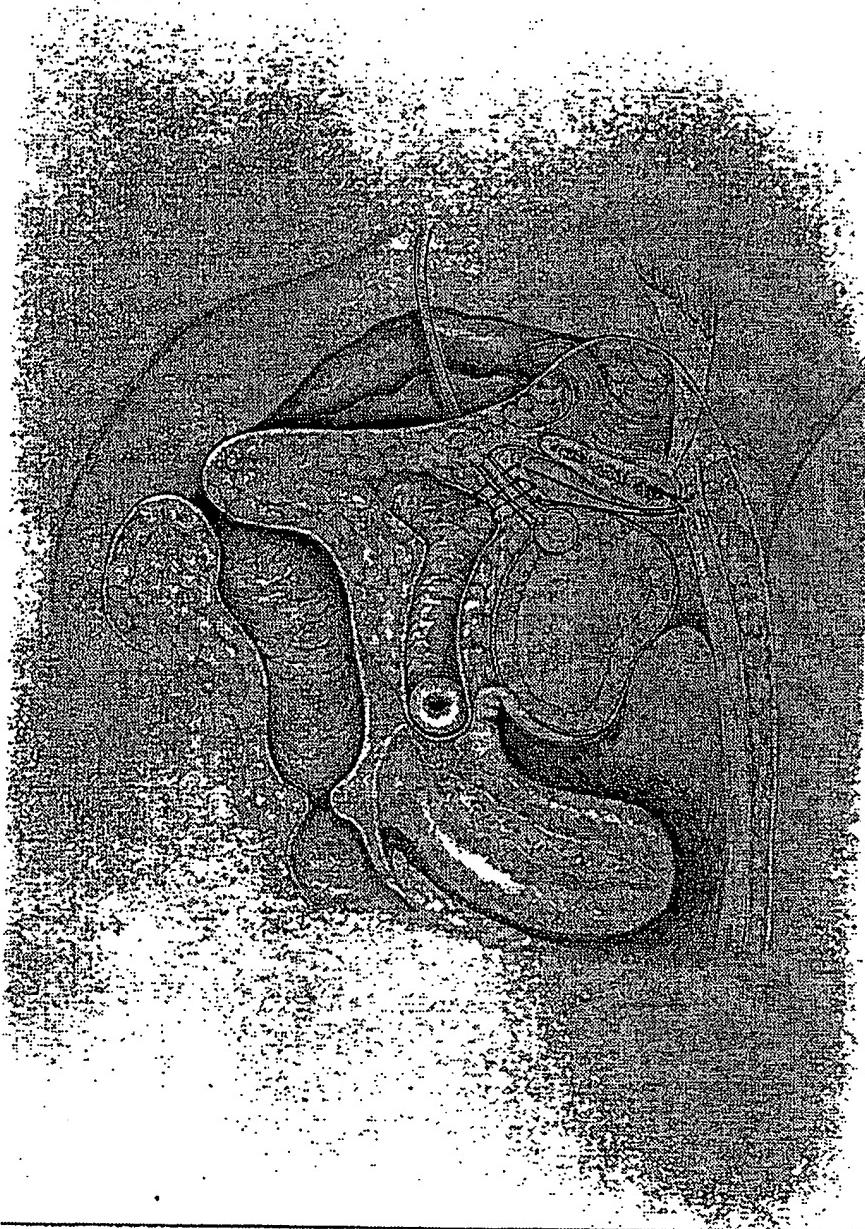
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FIGURE 13B



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FIGURE 14



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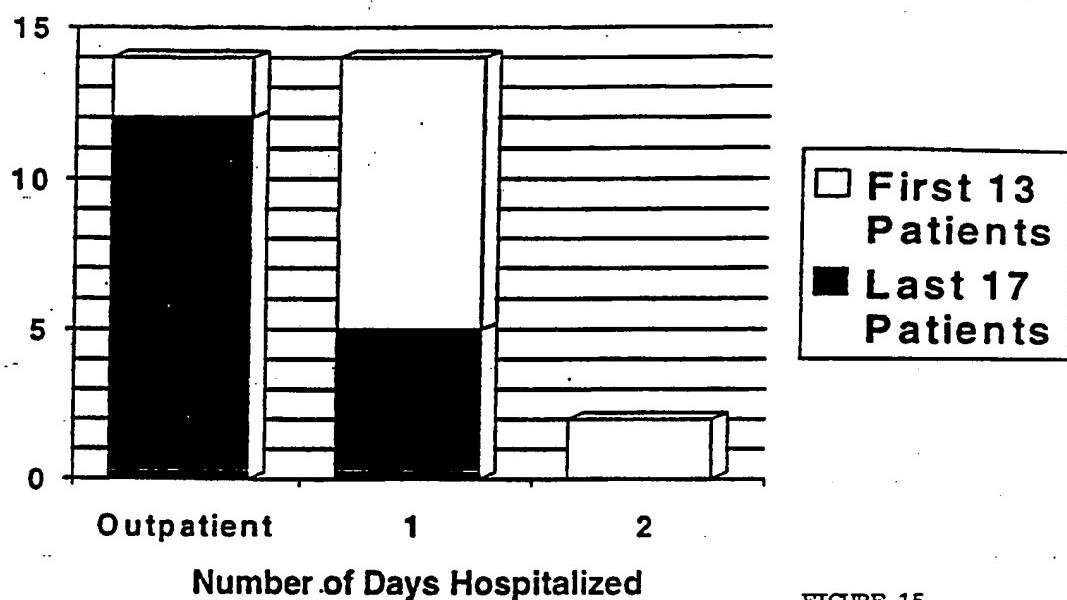
**Number of Patients**

FIGURE 15

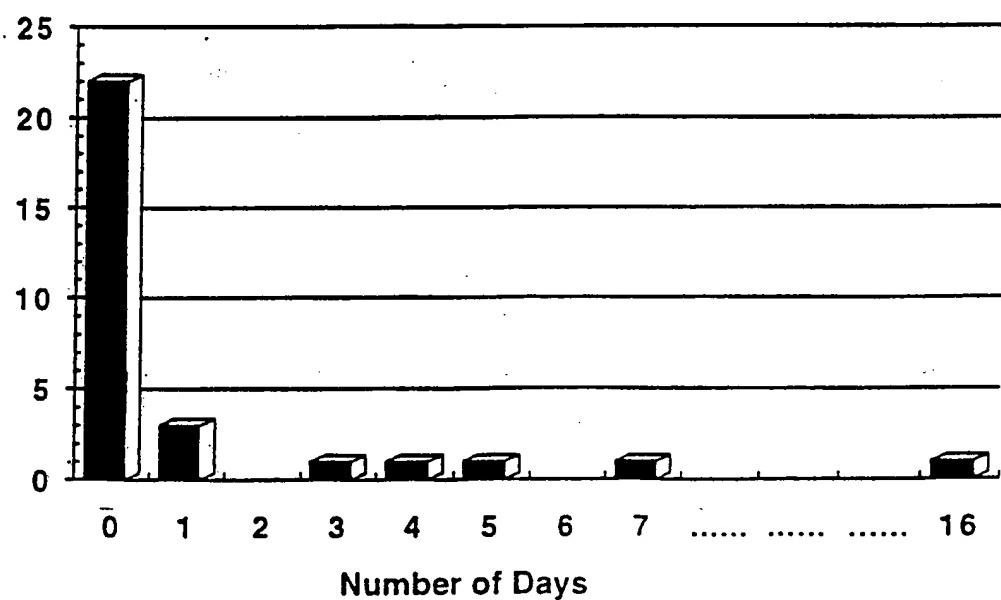
**Number of Patients**

FIGURE 16

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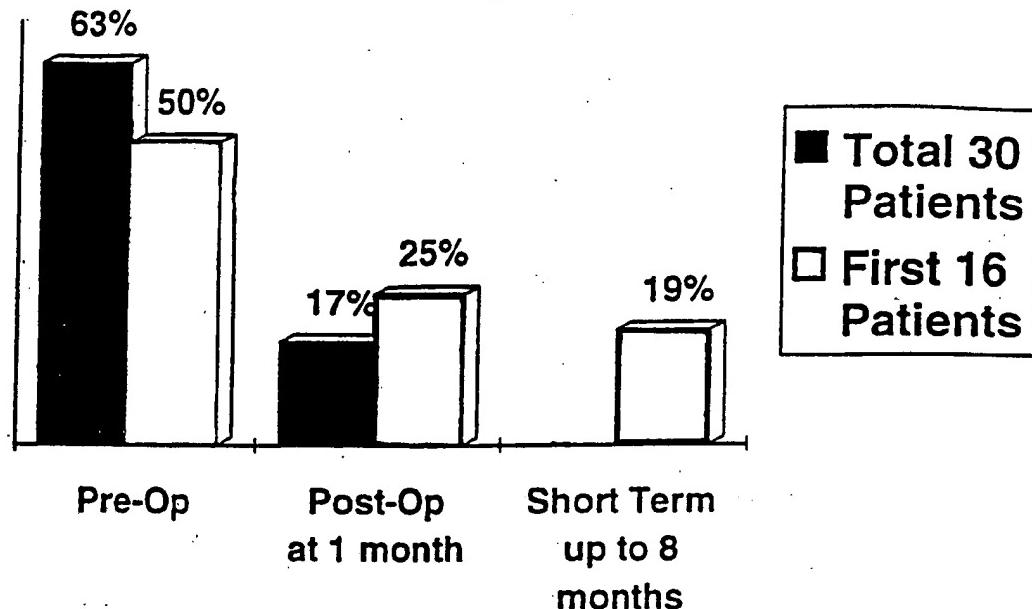


FIGURE 17

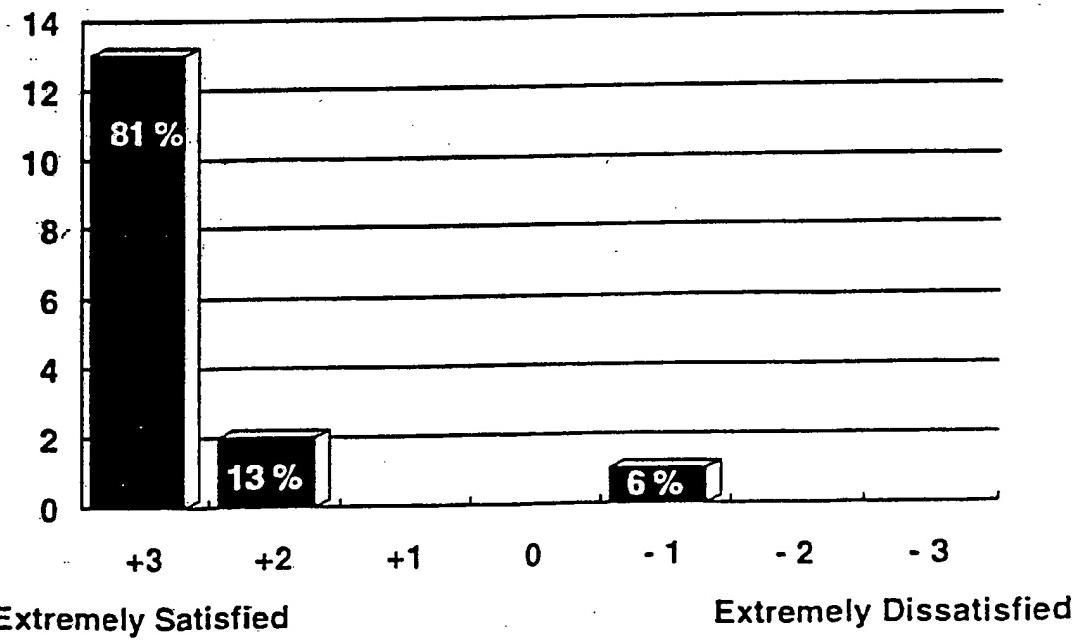
**Number of Patients**

FIGURE 18

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